IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

KATHERINE L. HALL,

Plaintiff,

v. CIVIL ACTION NO. 2:12-cv-08186

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

The following motions have been brought by the defendant, Boston Scientific Corporation: (1) Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [Docket 55]; (2) Motion to Exclude the Opinions and Testimony of Alison Vredenburgh, Ph.D., CPE [Docket 57]; (3) Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 69]; (4) Motion to Exclude the Opinions and Testimony of Thomas H. Barker [Docket 72]; (5) Motion to Exclude the Opinions and Testimony of Richard W. Trepeta, M.D. [Docket 84]; (6) Motion to Exclude the Opinions and Testimony of Donald R. Ostergard, M.D. [Docket 89]; (7) Motion to Exclude the Plaintiff's Experts' Opinion that Polypropylene Mid-Urethral Slings Are Defective [Docket 93]; (8) Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. and Samuel P. Gido, Ph.D. [Docket 99]; (9) Motion to Exclude the Testimony of Mark Slack [Docket 120]; and (10) Motion to Exclude the Testimony of Peggy Pence [Docket 130].

The following motions have been brought by the plaintiff, Katherine L. Hall: (1) Motion to Limit the Opinions and Testimony of Patrick Culligan, M.D. [Docket 91]; (2) Motion to Limit the Opinions and Testimony of Peter Finamore, M.D. [Docket 116]; (3) Motion to Exclude or Limit the Testimony of Defendant Boston Scientific Corporation's Expert Christine Brauer, Ph.D. [Docket 118]; and (4) Motion to Clarify the Memorandum Opinion and Order Entered in *Sanchez v. Boston Scientific, Corp.* [Docket 155].

My rulings are as follows: BSC's Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [Docket 55]; Motion to Exclude the Opinions and Testimony of Richard W. Trepeta, M.D. [Docket 84]; Motion to Exclude the Opinions and Testimony of Donald R. Ostergard, M.D. [Docket 89]; Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. and Samuel P. Gido, Ph.D. [Docket 99]; and Motion to Exclude the Testimony of Peggy Pence [Docket 130] are **GRANTED in part** and **DENIED in part**. BSC's Motion to Exclude the Opinions and Testimony of Alison Vredenburgh, Ph.D., CPE [Docket 57]; Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 69]; Motion to Exclude the Opinions and testimony of Thomas H. Barker [Docket 72]; and Motion to Exclude the Testimony of Mark Slack [Docket 120] are **GRANTED**. And BSC's Motion to Exclude the Plaintiffs' Experts' Opinions that Polypropylene Mid-Urethral Slings Are Defective [Docket 93] is **DENIED**.

The plaintiff's Motion to Limit the Opinions and Testimony of Patrick Culligan, M.D. [Docket 91] is **GRANTED in part** and **DENIED as moot in part**. The plaintiff's Motion to Limit the Opinions and Testimony of Peter Finamore, M.D. [Docket 116] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**. The plaintiff's Motion to Exclude or Limit

the Testimony of Defendant Boston Scientific Corporation's Expert Christine Brauer [Docket 118] is **GRANTED**. The plaintiff's Motion to Clarify [Docket 155] is **DENIED**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 15,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. In this particular case, the plaintiff, Katherine Hall, was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System ("Obtryx"), a mesh product manufactured by BSC to treat SUI. Ms. Hall received her surgery at Gundersen Lutheran Hospital in La Crosse, Wisconsin, on October 12, 2006. (Pl. Fact Sheet [Docket 59-2], at 6). She now claims that as a result of the implantation of the Obtryx, she has developed various complications, including mesh erosion, lower abdominal pain, pelvic pressure, burning sensations, and renewed SUI. (*See id.* at 7). The plaintiff advances the following claims against BSC: negligence; strict liability for design defect, manufacturing defect, and failure to warn; breach of express and implied warranties; and fraudulent concealment. (*See* Second Am. Short Form Compl. [Docket 109] ¶ 13). The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1)

helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper.[1] It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability

[1] With more than 70,000 cases related to surgical mesh products currently pending before me, this gatekeeper role takes on extraordinary significance. Each of my evidentiary determinations carries substantial weight with the remaining surgical mesh cases. Regardless, while I am cognizant of the subsequent implications of my rulings in these cases, I am limited to the record and the arguments of counsel.

determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Finally, in several of the instant *Daubert* motions, a specific scientific methodology comes into play, dealing with differential diagnoses or etiologies. "Differential diagnosis, or

differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262. The Fourth Circuit has stated that:

> A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. A reliable differential diagnosis passes scrutiny under *Daubert*. An unreliable differential diagnosis is another matter:

> A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation. However, "[a] medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." The alternative causes suggested by a defendant "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony," unless the expert can offer "no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause."

Id. at 265–66 (internal citations omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

Before I review these motions, I begin by addressing three arguments that apply to many of the parties' *Daubert* objections. Unless otherwise necessary, I will not address these objections again specific to each challenged expert. First, as I have maintained throughout these MDLs, I will not permit the parties to use experts to usurp the jury's fact-finding function by

allowing an expert to testify as to a party's state of mind or on whether a party acted reasonably. *See, e.g.*, *Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, at *3 (S.D. W. Va. July 8, 2014); *Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013). Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.

Second, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). I have diligently applied this rule to previous expert testimony, and I continue to adhere to it in this case. I will not parse the expert reports and depositions of each expert in relation to these same objections. I trust that able counsel in this matter will tailor expert testimony at trial accordingly.

Last, with respect to the arguments that certain experts' testimony is litigation driven, I note that an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion. *See Daubert v. Merrell Dow Pharm., Inc.* ("*Daubert II*"), 43 F.3d 1311, 1317 (9th Cir. 1995) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture."). This concern, however, does have a role in applying *Daubert*. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007) (considering in the *Daubert* analysis "[w]hether experts are proposing to testify about

matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" (quoting Fed. R. Evid. 702 advisory committee's note)). In sum, I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. But I will consider the independence of an expert's testimony as evidence that his "research comports with the dictates of good science." *Daubert II*, 43 F.3d at 1317. Having addressed these universal objections, I now turn to BSC's *Daubert* motions.

III. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude the expert opinions of Michael Thomas Margolis, M.D., Alison Vredenburgh, Ph.D., CPE, Vladimir Iakovlev, M.D., Thomas H. Barker, Ph.D., Richard W. Trepeta, M.D., Donald R. Ostergard, M.D., Dr. Jimmy W. Mays, Ph.D., Dr. Samuel P. Gido, Ph.D., Dr. Mark Slack, and Dr. Peggy Pence. BSC also seeks to preclude the plaintiffs' experts from opining on the alleged defects of polypropylene mid-urethral slings.

A. Motion To Exclude the Plaintiff's Experts' Opinion that Polypropylene Mid-Urethral Slings Are Defective

BSC moves to exclude the plaintiff's experts' opinion that polypropylene mid-urethral slings are defective. I have previously reviewed an identical motion. *See Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *4–5 (S.D. W. Va. Sept. 29, 2014). The parties in this case assert the same arguments and to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. In *Sanchez*, I ruled as follows:

> Rule 702, by its plain terms, contemplates *Daubert* challenges directed at the opinions of *specific* experts, not the opinions of a collection of experts. While these experts may have come to similar conclusions, it is not the conclusions that the court must assess, but the reliability of the methods and procedures

> underpinning those conclusions. *Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."). Two experts may come to a similar conclusion, but one or both experts' methodology in reaching that conclusion may be unreliable. Rule 702 directs the court to determine whether *an expert* is qualified, whether his or her opinions are the product of reliable methodology, and whether the opinions will be helpful to the jury. *See* Fed. R. Evid. 702. I can only conduct the required *Daubert* analysis on an individualized basis.

Id. at 5. Accordingly, I **ADOPT** my prior ruling with regard to the plaintiff's experts, as stated in *Sanchez*, and **DENY** BSC's motion.

B. Motion to Exclude the Testimony of Michael Thomas Margolis, M.D.

BSC moves to exclude the expert opinions of Michael Thomas Margolis, M.D. Dr. Margolis is a urogynecologist who offers general causation opinions regarding alleged defects of polypropylene transvaginal mesh and polypropylene mid-urethral slings. I have previously reviewed the expert opinions of Dr. Margolis under *Daubert*. *See Sanchez*, 2014 WL 4851989, at *10-19. The parties in this case assert the same arguments and to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material.

1. Failure to Scientifically Consider the Evidence

First, BSC argues that Dr. Margolis's opinions are unreliable because they are based on a biased and incomplete review of the medical literature.

a. Safety and Efficacy of Mid-Urethral Slings

BSC contends that Dr. Margolis ignored published, peer-reviewed medical literature demonstrating that polypropylene mid-urethral slings are safe and effective to treat SUI. In *Sanchez*, I ruled as follows:

> BSC's argument focuses on Dr. Margolis's testimony regarding the *Nilsson* seventeen-year follow-up study, which supports the conclusion that polypropylene slings are safe and effective. (*See* Margolis Dep. [Docket 132-2], at 193:5–20). Dr. Margolis rejected the *Nilsson* study without explaining a scientific

basis for doing so. Instead, he merely indicated that he had "serious questions about the bias, the potential for bias and also the – the data in this article" but would not elaborate further:

> Q: You believe that this particular study is – is not reliable; is that your opinion?
>
> A: I question the reliability.
>
> Q: And you won't tell me why?
>
> A: I question it, and that's all I can say.
>
> . . .
>
> Q: So what you're telling the judge is I am dismissing this paper and not considering it reliable, but I'm not going to tell you why?
>
> A: Sure. I don't have to tell you why I don't consider something to be authoritative. I mean, I don't consider that to be a valid study. I have concerns about it. I have a right to hold that opinion. And I do hold that opinion.
>
> Q: All right. Are there and –
>
> A: I don't consider it authoritative and I consider it potentially flawed and potentially biased. That's my opinion. Right or wrong, that's my opinion.

Id. at *12. I **ADOPT** my prior ruling, as stated in *Sanchez*, and **FIND** that Dr. Margolis's method is unreliable. Accordingly, this opinion is **EXCLUDED**.

b. Complication Rates of Pain

BSC contends that Dr. Margolis failed to consider published studies showing the complication rate of pain with polypropylene slings is lower than the complication rate he seeks to offer in this case. In *Sanchez*, I cited to Dr. Margolis's deposition testimony, which reveals that he gives no scientific basis for disagreeing with these studies:

> Q: Would you agree that there are studies that show that the rates of pain with polypropylene slings are in the low single digits?
>
> . . .
>
> A: I – there are studies.
>
> Q: And do you discount those studies?
>
> A: I disagree with those studies.
>
> Q: And why?
>
> A: Because that's not what I have seen, read, studied, observed, and that's not biologically plausible.

([Margolis Dep. [Docket 132-2],] at 239:2–13). Without further explanation for his disagreement with these studies, Dr. Margolis's method is unreliable.

Id. at *13. Accordingly, I **ADOPT** my prior ruling, as stated in *Sanchez*, and **EXCLUDE** this opinion.

c. Complication Rates

BSC contends that in reaching his opinions on the complication rates in women with polypropylene mesh, Dr. Margolis did not review the literature as a scientist. In *Sanchez*, I cited to Dr. Margolis's deposition testimony, where he explains his belief that studies indicating low single digit complication rates are not accurate because complications are underreported and data is possibly fabricated. *See id.* at *13. I also **FIND** that Dr. Margolis's method of "[g]iv[ing] the benefit of the doubt to the patient" is unreliable:

> Dr. Margolis explains that, when forming his opinion about the complication rates of a medical procedure, he "give[s] the benefit of the doubt to the patient." ([Margolis Dep. [Docket 132-2],] at 259:7–9). In other words, he "assume[s] the worst-case scenario" and errs on the side of opining as to a higher complication rate to better protect a patient. (*Id.* at 259:11–259:23). Dr. Margolis eventually admits that he has been evaluating the literature and forming his opinions for this case according to that principle as well. (*See id.* at 259:20–260:14). "[G]iv[ing]

> the benefit of the doubt to the patient" is not a scientific basis for determining the complication rates associated with a mesh device. (*Id.* at 259:8–9).

Id. at *14. Accordingly, I **ADOPT** my prior ruling, as stated in *Sanchez*, and **EXCLUDE** this opinion.

2. Unreliable Based on Personal Experience

Next, BSC argues that Dr. Margolis fails to support several of his expert opinions with reliable facts or data.

a. Lack of Sound Scientific Evidence

BSC contends that Dr. Margolis provides no basis for his opinion that there is a lack of sound scientific evidence supporting the clinical benefits of polypropylene mesh. In *Sanchez*, I ruled as follows:

> Inconsistent statements of a witness may be addressed on cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994) ("[E]valuating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses ..."). However, here, Dr. Margolis's inconsistencies seem to directly shed light on the unreliability of his method. Even if Dr. Margolis is stating that there is a lack of *credible* evidence, as the plaintiffs argue, it is still unclear why Dr. Margolis believes these studies lack credibility. As a result, Dr. Margolis's opinions are rendered untrustworthy and unreliable.

Id. at *14. Accordingly, I **ADOPT** my prior ruling, as stated in *Sanchez*, and **EXCLUDE** this opinion.

b. Burch Procedure

BSC contends that Dr. Margolis provides no basis for his opinion that the Burch procedure is more effective than a polypropylene mid-urethral sling. In *Sanchez*, I ruled as follows:

> Dr. Margolis cited in his report several scientific, peer-reviewed sources showing that the Burch procedure has high success rates. (*See* Margolis Report [Docket 58-1], at 9 n.6 (citing J.W. Ross, *Post Hysterectomy Total Vaginal Vault Prolapse Repaired Laparoscopically*. Presented at 2nd World Symposium on Laparoscopic Hysterectomy, American Association of Gynecologic Laparoscopists, New Orleans, LA (Apr. 7–9, 1995) (reporting 93% success rate for laparoscopic Burch and 90% for open Burch in the treatment of SUI); Romano S. Bustan et al., *Burch Laparoscopic Procedure for Repairing Proven Stress Incontinence—Report of 32 Cases*, Harefuah 139 (9–10), 350–52, 407 (2000) (reporting 97% cure rate); E.G. Jacome et al., *Laparoscopic Burch Urethropexy in a Private Clinical Practice*, J. Am. Assoc. Gynecol. Laparosc. 6(1): 39–44 (1999) (reporting cure rate of 94% for laparoscopic Burch); R.D. Moore et al., *Laparoscopic Burch Colposuspension for Recurrent Stress Urinary Incontinence*, Jourdan of the Am. Assoc. of Gyneco. Laparasc. 8, no.8:389–92 (2001) (reporting 90% objective cure rate in patients having repeat Burch procedure laparoscopically); Todd R. Jenkins and C.Y. Liu, *Laparoscopic Burch Colposuspension*, 4 Current Opinion in Obstetrics & Gynec. 314, 314–18 (2007) (literature review noting a finding of cure rates between 76% to 95% for laparoscopic Burch procedures)). In addition, Dr. Margolis testified that the Burch procedure success rates reported in the data are higher than the rates for the polypropylene sling. (*See* Margolis Dep. [Docket 132-1], at 136:12–16).

Id. at *15. Accordingly, I **ADOPT** my prior ruling, as stated in *Sanchez*, and **FIND** that Dr. Margolis's opinion is reliable.

c. Xenform Slings

BSC contends that Dr. Margolis provides no basis for his opinion that Xenform slings are more effective than polypropylene slings. In *Sanchez*, I ruled as follows:

> Although Dr. Margolis has experience in this area, his method of comparing the complication rates of Xenform and polypropylene slings is problematic. In his deposition, Dr. Margolis explained that the 4% complication rate for Xenform slings is, in fact, "the complication rate that I understand all surgeons have when they take any patient into an operating room, whether it's vaginal surgery, abdominal surgery, bladder surgery, brain surgery, or toe surgery." (Margolis Dep., [Docket 132-1], at 122:18–24). His reasoning as to why Xenform has a lower complication rate than polypropylene slings is simply because Xenform uses no polypropylene mesh and, thus, has no mesh-related complications. (*See id.* at 123:22–124:11). This logic is not scientific. Dr. Margolis's conclusion that Xenform does not have mesh-related complications because it is not made from mesh could be reached by a jury without expert testimony.

> Moreover, Dr. Margolis cannot cite a single study involving use of Xenform slings to treat SUI. When asked if he could point to a study, Dr. Margolis responded "I am not prepared to present any studies to you today. I don't know any off the top of my head." (*Id.* at 133:14–19). When asked if he had seen any studies, Dr. Margolis testified "I'm sure I have. I don't have any names for you today." (*Id.* at 133:20–24). Without a scientific basis, Dr. Margolis's method is unreliable.

Id. at *16. Accordingly, I **ADOPT** my prior ruling, as stated in *Sanchez*, and **EXCLUDE** this opinion.

d. Infection Rate

BSC contends that Dr. Margolis provides no basis for his opinion that the infection rate of polypropylene mesh is 100%. In *Sanchez*, I ruled as follows:

> Dr. Margolis's inconsistent presentation does not automatically render his method unreliable. In his report, Dr. Margolis does cite to scientific studies to support his opinion. (*See* Margolis Report [Docket 58-1], at 16) (describing the *Vollebregt* study finding 83.6% of implants contained bacteria during surgical implantation, the *Boulanger* study finding 100% of mesh explants removed in the study due to complications contain bacteria, the *Shah* and *Badlani* study finding infection in mesh patients).
>
> However, as BSC points out, the study which Dr. Margolis cites to support his 100% figure is not directly applicable. The *Boulanger* study did not find that 100% of the mesh systems explanted for the study were infected; the study found that 100% of the mesh systems were contaminated with bacteria. (*See* Margolis Report [Docket 58-1], at 16; Boulanger et al., *Bacteriological Analysis of Meshes Removed for Complications After Surgical Management of Urinary Incontinence or Pelvic Organ Prolapse*, 19 Int'l Urogynecol J. 827, 827 (2008) [Docket 58-5]). The authors of the *Boulanger* study are not certain that bacteria contamination leads to infection. (*See* Boulanger, *supra*, at 827, 830) (stating that the "exact role" of bacterial contamination "is not yet clear" and "must be explored by other experimental studies")). They even write that "[i]nfection is a rare complication of retropubic mid-urethral slings (0.7% of cases)" and that their "findings concur with previously published data" on this subject. (Boulanger, *supra*, at 830).
>
> The *Boulanger* study does not support the opinion that there is a 100% infection rate in women who undergo mesh implantation surgery. Therefore, Dr. Margolis's methodology of basing his opinion on this study is unreliable.

Id. at *17. Accordingly, I **ADOPT** my prior ruling, as stated in *Sanchez*, and **EXCLUDE** this opinion.

e. Urethral Obstruction

BSC contends that Dr. Margolis provides no basis for his opinion that the complication rate of urethral obstruction is greater than 10% with polypropylene mid-urethral slings. Dr. Margolis opines that polypropylene mid-urethral slings cause urethral obstruction in more than 10% of patients but could not point to scientific studies in support of his opinion:

> Q: . . . [A]re you offering an opinion as to how frequently shrinkage of a polypropylene midurethral sling chokes off the vagina as a result of shrinkage?
>
> A: Yes.
>
> Q: How often?
>
> A: Greater than ten percent.
>
> Q: And is there a study that you're relying upon for that?
>
> A: I'm looking. And I'm not finding it right now. So I don't have a study for you at this time.

(Margolis Dep. [Docket 55-2], at 262:6–16). The plaintiff does not respond to this argument. Consistent with my ruling in *Sanchez*, I **FIND** that without a scientific basis, Dr. Margolis's opinion is unreliable, and thus, **EXCLUDED**.

f. Products Removed

BSC contends that Dr. Margolis provides no basis for his opinion on the percentage or number of BSC products he has removed. In *Sanchez*, I ruled as follows:

> Dr. Margolis testified that he has removed approximately 300 polypropylene mesh and sling products "throughout the last 15 or so years" and gives his "best guess" that 10% to 15% of those were Boston Scientific. (Margolis Dep. [Docket 132-1], at 74:23–76:1). Dr. Margolis explained that "[t]he exact numbers of each

> [product] I don't keep track of." (*Id.* at 74:11–19). When asked how he arrived at that 10% to 15% figure for Boston Scientific products, Dr. Margolis testified that these percentages are just to his "best recollection":
>
> > Q: Have you tried to do a system—did you go back and try to do some kind of systematic count, or are you just doing that from recollection in terms of the percentage of Boston Scientific products?
> >
> > A: Best recollection.
>
> (*Id.* at 76:13–18). Dr. Margolis testified that he cannot identify the mesh brand by sight after explantation, and he "tr[ies] to get the operative records from the implant" with the product manufacturing information but does not know how often he receives these records for his patients. (*Id.* at 76:2–9, 77:14–78:2).
>
> As a result, BSC argues that Dr. Margolis's opinion as to the number or percentage of BSC products he has removed is unreliable.
>
> Without a reliable basis, Dr. Margolis's opinions may be erroneous. *See Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014) (excluding expert's "analyses of the mesh implants" because they were not "controlled for error or bias"). Therefore, his opinions are **EXCLUDED**.

Sanchez, 2014 WL 4851989, at *18. Accordingly, I **ADOPT** my prior ruling, as stated in *Sanchez*, and **EXCLUDE** this opinion.

3. Qualifications

Lastly, BSC argues that Dr. Margolis is not qualified to opine on biomaterials, adequate pore size, adequate weight of polypropylene, polypropylene degradation, biocompatibility of polypropylene, medical device design and development, and marketing. The plaintiff concedes that Dr. Margolis will not offer opinions outside the scope of his knowledge as a surgeon and urogynecologist. Accordingly, BSC's motion is **DENIED as moot**.

In sum, BSC's motion with regard to Dr. Margolis is **GRANTED in part** and **DENIED in part**.

C. Motion to Exclude the Opinions and Testimony of Alison Vredenburgh, Ph.D., CPE

Dr. Vredenburgh works as a consultant and researcher in the field of "human factors," providing business guidance on matters such as product warning design, injury prevention, risk management, and warning effectiveness. (*See* Vredenburgh Curriculum Vitae [Docket 57-2], at 2 (describing Dr. Vredenburgh's current consulting position)). The plaintiff offers Dr. Vredenburgh to provide expert testimony on various topics related to the "general principles of human factors psychology and BSC's failure to correctly apply those principles." (Pl.'s Opp. to BSC's Mot. to Exclude the Ops. & Test. of Dr. Vredenburgh ("Pl.'s Opp. re: Vredenburgh") [Docket 78], at 4). In sum, Dr. Vredenburgh opines that "BSC failed to effectively control the hazards present in its transvaginal mesh products at issue in this litigation, including its design and hazard communication (including instructions, training, and warnings)." (Vredenburgh Report [Docket 57-1], at 4).

BSC's objections to this expert testimony fall into four categories: (1) Dr. Vredenburgh is not qualified to offer the opinions set forth in her report; (2) Dr. Vredenburgh did not support her opinions with reliable methodology; (3) Dr. Vredenburgh's opinions are not helpful to the jury; and (4) Dr. Vredenburgh's opinions are not proper for expert testimony because they assert legal conclusions and opine about BSC's state of mind. Because I find that Dr. Vredenburgh's opinions are improper and therefore not helpful to the jury as prescribed by Federal Rule of Evidence 702, I need not address BSC's arguments regarding Dr. Vredenburgh's qualifications and the reliability of her methods. As further explained below, I **GRANT** BSC's Motion to Exclude the Opinions and Testimony of Dr. Vredenburgh [Docket 57].[2]

1. Improper Legal Conclusions

[2] I also note that the dismissal of the plaintiff's failure-to-warn claim renders the majority of Dr. Vredenburgh's opinions irrelevant and therefore inadmissible. *See Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.").

Rule 702 provides that an expert witness may testify in the form of an opinion if his or her "specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). If, for instance, an expert's opinion "supplies the jury with no information other than the witness's view of how the verdict should read," then the testimony is essentially a legal conclusion "that is better handled by the judge and, coming from the witness, will be of little assistance to the jury." *United States v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011). Dr. Vredenburgh's testimony collapses under this rule. Instead of simply outlining her opinion on the vital parts of a product warning, Dr. Vredenburgh's report goes a step further, concluding that BSC "failed to provide warnings or instructions to adequately inform users of the dangers associated with using the device." (Vredenburgh Report [Docket 57-1], at 6). As I held in *In re C. R. Bard, Inc.*, "whether [the defendant] failed to warn [is a] question[ ] for the jury, not for Dr. [Vredenburgh]." 948 F. Supp. 2d 589, 629 (S.D. W. Va. 2013); *see also Strong v. E.I. DuPont de Nemours Co.*, 667 F.2d 682, 686 (8th Cir. 1981) ("[T]he question of whether the lack of warnings rendered the . . . products unreasonably dangerous is not the kind of issue on which expert assistance is essential for the trier of fact. The jury was capable of drawing its own inferences from the available evidence."). Accordingly, I **EXCLUDE** Dr. Vredenburgh's opinions, as they are all based on legal conclusions.

2. Improper State of Mind Testimony

Dr. Vredenburgh's expert report also offers opinions on BSC's state of mind and corporate conduct. Specifically, Dr. Vredenburgh states that BSC: "*knew* the complication rates, yet failed to include them in the warnings and/or labeling"; "*was aware* of debilitating outcomes"; used "anti-warnings" to "*deliberately misrepresent* dangerous products as safe"; and "*refused* to perform Clinical Testing to help identify risks." (Vredenburgh Report [Docket 57-1],

at 10–20 (emphasis added)). As I have previously stressed, the defendant's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *In re C. R. Bard, Inc.*, 948 F.Supp.2d at 611 (citing to *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony.")). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance from time immemorial." *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998). Here, opinions on BSC's alleged corporate misconduct and improper decisions are strewn throughout Dr. Vredenburgh's report, largely supported by various BSC internal documents. (*See, e.g.*, Vredenburgh Report [Docket 57-1], at 6 (citing to the depositions of BSC corporate executives)). While internal corporate documents and executives' testimony are certainly relevant in this case, such evidence "should be presented directly to the jury, not through an expert." *In re C. R. Bard, Inc.*, 948 F. Supp. 2d at 628. Thus, I **EXCLUDE** Dr. Vredenburgh's opinions on BSC's state of mind, corporate knowledge, business failures, and the like.

In conclusion, Dr. Vredenburgh's expert report provides legal conclusions about whether BSC acted appropriately and opines about BSC's corporate ethics. The jury is capable of evaluating the evidence on these subjects without the help of an expert. Furthermore, the court believes her testimony as offered would mislead and confuse the jury, even if arguably adequate under *Daubert*. Therefore, I **GRANT** BSC's Motion to Exclude the Opinions and Testimony of Dr. Vredenburgh [Docket 56].

D. Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D.

BSC seeks to exclude the expert opinions offered by Vladimir Iakovlev, M.D. Dr. Iakovlev is an anatomical pathologist who offers opinions on pathological and morphological findings with regard to mesh and mesh products. I have previously reviewed the expert opinions of Dr. Iakovlev under *Daubert*. *See Tyree, et al. v. Boston Scientific Corp.*, ___ F. Supp. 3d ___, *39–43 (S.D. W. Va. 2014), *available at* 2014 WL 5320566. The parties in this case assert the same arguments and to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material.

1. General Causation Opinions

First, BSC argues that Dr. Iakovlev's general causation opinions based on the Bendavid study should be excluded because they are unreliable. In *Tyree*, I ruled as follows:

> In preparing his expert report, Dr. Iakovlev examined over 100 mesh explants, approximately twenty percent of which were polypropylene and some fraction of which were transvaginal. (Iakovlev Report [Docket 225-1], at 2; Iakovlev Dep. [Docket 225-3], at 55, 243). The explanted mesh types included woven, knitted, printed, GoreTex, combined designs of different manufacturers, and 21 samples from BSC. (Iakovlev Report [Docket 225-1], at 2; Iakovlev Dep. [Docket 225-3], at 320). BSC argues that because the study was not confined to polypropylene mesh and Dr. Iakovlev provides no information on how the mesh explants were chosen, the results are irrelevant and unreliable. The plaintiffs contend that Dr. Iakovlev's independent scientific testing is grounded in reliable methodology because he saw nerve entrapment, nerve ingrowth and degradation in 100% of the BSC explants. (Pls.' Opp. to Def.'s Mot. to Exclude the Ops. & Test. of Vladimir Iakovlev, M.D. ("Pls.' Opp. re: Iakovlev") [Docket 268], at 9).
>
> Although BSC fails to cite to any testimony from Dr. Iakovlev supporting its premise, I agree that Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. (Def.'s Mem. re: Iakovlev [Docket 226], at 5–6). Dr. Iakovlev testified that the 21 BSC samples he examined were provided by plaintiffs' counsel. (Iakovlev Dep. [Docket 268-2], at 42). I also note, in his deposition for *Edwards*, Dr. Iakovlev further testified that he requested all available meshes for examination, but had no way of knowing what methodology the plaintiffs' lawyers employed in providing him with the number of meshes they did. (*Id.* at 157–61). Dr. Iakovlev "has given no explanation as to whether [his] is a representative sample size or how he chose the

> particular explants analyzed." *Lewis*, 2014 WL 186872, at *8. "Therefore, I have no information as to the 'potential rate of error' inherent in [his] observations." *Id.* (citing *Daubert*, 509 U.S. at 594). By simply highlighting the fact that Dr. Iakovlev performed an independent analysis, the plaintiffs have not demonstrated that Dr. Iakovlev's opinions regarding pelvic mesh explants were derived using scientific methods. Therefore, Dr. Iakovlev's general causation opinions related to the Bendavid study are **EXCLUDED**.

Id. at *40–41. Accordingly, I **ADOPT** my prior ruling, as stated in *Tyree*, and **EXCLUDE** Dr. Iakovlev's general causation opinions related to the Bendavid study.

2. Stretch Test

BSC argues that Dr. Iakovlev's opinions on deformation based on the stretch test should be excluded because they are unreliable. In *Tyree*, I ruled as follows:

a. Testing Standards

> Many of BSC's arguments incorporate Dr. Iakovlev's failure to adhere to testing standards or a written protocol. In his deposition, Dr. Iakovlev states that he developed the stretch test method; however, he failed to follow a written protocol other than the brief description included in his expert report. (Iakovlev Dep. [Docket 225-3], at 345). When describing the methodology he employed, Dr. Iakovlev admits that he did not wear gloves, clean or sterilize the mesh, or use machinery to regulate the amount of force exerted. (*Id.* at 347–48). Dr. Iakovlev insists that because the criterion for the test was length rather than force, the regulation of force was irrelevant. (*Id.* at 348). Nevertheless, Dr. Iakovlev readily admits that he developed and performed the stretch test himself, without taking care to standardize his method or the results. (*Id.* at 345, 350). Additionally, Dr. Iakovlev has no knowledge of whether his methodology is generally accepted in the medical community. (*Id.* at 350). Finally, when asked how he can be sure his results were not caused by the way he pulled the mesh, Dr. Iakovlev's only response is that the stretch test was a simulation, which I **FIND** insufficient to establish reliability. (*Id.* at 351–52).

b. In Vivo Environment

> BSC's remaining two arguments are in regard to Dr. Iakovlev's failure to replicate an in vivo environment. Although Dr. Iakovlev states that he performed the stretch test to simulate forces acting on the device in the body, BSC contends that Dr. Iakovlev has no way of knowing whether mesh responds to stretching with clamps the same way it does when implanted inside of a woman. (Def.'s Mem. re: Iakovlev [Docket 226], at 7). BSC further argues that Dr. Iakovlev's

> tests failed to replicate the forces in the female pelvic floor because he measured uniaxial forces, while the forces in the female pelvic floor are generally multi-directional. (*See id.*).
>
> The mere fact that Dr. Iakovlev's study was uniaxial does not alone render his methodology unreliable; however, the fact that he did not account for multi-directional forces inside of the female pelvis weighs heavily against admissibility. Much like his response to BSC's question regarding confirmation bias, when asked about the way mesh responds inside and outside of the body, Dr. Iakovlev states that "the assumption is that if the forces are similar, the behavior will be similar. That's a limitation of all experimental studies." (Iakovlev Dep. [Docket 225-3], at 352). Dr. Iakovlev's "assumption" that the force he applied by pulling on the clamps accurately represents the forces inside the human body is hardly sufficient to survive *Daubert* scrutiny. Accordingly, I **FIND** that Dr. Iakovlev's opinions based on his "stretch test" are unreliable and thus, **EXCLUDED**.

Id. at *41–43 (footnotes omitted). Accordingly, I **ADOPT** my prior ruling, as stated in *Tyree*, and **EXCLUDE** Dr. Iakovlev's opinions based on his stretch test.

3. Mesh Design and Polypropylene Degradation

BSC argues that Dr. Iakovlev's opinions on deformation of mesh based on mesh design and his opinions on polypropylene degradation should be excluded because they are beyond his qualifications and unreliable. With regard to Dr. Iakovlev's qualifications, in *Tyree*, I held as follows:

> A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information. *Edwards v. Ethicon*, No. 2:12-cv-09927, 2014 WL 3361923, at *24 (S.D. W. Va. July 8, 2014) (citation omitted). In his expert report, Dr. Iakovlev states that his "professional activities include diagnostic examination of specimens removed surgically or by biopsies from the human body, where [his] annual practice volume amounts to 5000 cases." (Iakovlev Expert Report [Docket 225-1], at 1). Dr. Iakovlev also teaches a course on anatomic pathology and cytology. (*Id.* at 29). BSC does not question Dr. Iakovlev's pathology credentials; rather, it only argues that as a pathologist, he is unqualified to render these opinions. However, throughout these MDLs, I have allowed numerous pathologists to testify regarding the properties of polypropylene mesh. *See, e.g.*, *Sanchez*, 2014 WL 4851989, at *19–20 (discussing Dr. Richard W. Trepeta); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) (discussing Dr. Bernd Klosterhalfen). In fact, in *Edwards*, I determined that Dr. Iakovlev was qualified

> to render an opinion regarding polypropylene degradation based on his experience as a pathologist. *See Edwards*, 2014 WL 3361923, at *24–25. The fact that Dr. Iakovlev took the time to familiarize himself with BSC's manufacturing process in no way diminishes his qualifications. Therefore, I **FIND** that Dr. Iakovlev is qualified to testify regarding mesh design, mesh deformation, and polypropylene degradation.

Id. at *40. Accordingly, I **ADOPT** my prior ruling, as stated in *Tyree*, and **FIND** that Dr. Iakovlev is qualified to opine on mesh design and polypropylene degradation.

With regard to reliability, it is clear that Dr. Iakovlev did not review samples separate from the Bendavid study and specific to the plaintiff because there was no pathological material from Ms. Hall to examine. (Iakovlev Report [Docket 69-1], at 9 ("There is no available material for pathology assessment of the explanted mesh specimens of Ms. Hall.")). In *Tyree*, I held as follows:

> In *Edwards*, I allowed Dr. Iakovlev to testify regarding Ms. Edward's mesh because his specific causation opinions did not present the same reliability concerns as his general causation opinions. 2014 WL 3361923, at *23 ("Dr. Iakovlev may not testify regarding his general conclusions about mesh because his choice of samples lacks scientific methodology. However, this is not a reason to exclude his testimony about Ms. Edward's mesh, which was made after a review of her explant."). Here, when discussing polypropylene degradation and his polarization technique, Dr. Iakovlev refers to the 21 BSC samples provided to him by plaintiffs' counsel. (Iakovlev Dep. [Docket 225-3], at 412). In his expert report, when discussing mesh design, Dr. Iakovlev states he examined a "variety" of BSC devices, but fails to indicate their source. Without more information, I must assume that Dr. Iakovlev's additional opinions are based on his general review of mesh explants as part of the Bendavid study, which I have determined to be unreliable. Therefore, I **FIND** that Dr. Iakovlev's opinions on mesh design, mesh deformation, and polypropylene degradation should also be **EXCLUDED**.

Tyree, 2014 WL 5320566, at *41. Accordingly, I **ADOPT** my prior ruling, as stated in *Tyree*, and **EXCLUDE** Dr. Iakovlev's opinions on mesh design, mesh deformation, and polypropylene degradation.

4. Specific Causation

BSC argues that Dr. Iakovlev's specific causation opinions should be excluded because they are unreliable and will not be helpful to a trier of fact. In *Eghnayem, et al. v. Boston Scientific Corp.*, I found Dr. Iakovlev's specific causation opinions reliable based on his "morphological differential diagnosis," which included an examination of the plaintiff's explanted mesh. *See* ___ F. Supp. 3d ___, *46 (S.D. W. Va. 2014), *available at* 2014 WL 5461991. In this case, there was no available material from Ms. Hall's explanted mesh for Dr. Iakovlev to examine and he did not perform a physical examination. Accordingly, I **FIND** that Dr. Iakovlev's specific causation opinions are not sufficiently reliable under *Daubert*, and thus, **EXCLUDED**.

In sum, BSC's motion with regard to Dr. Iakovlev is **GRANTED**.

E. Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D.

BSC seeks to exclude the expert opinions offered by Thomas H. Barker, Ph.D. Dr. Barker is a biomedical engineer who offers general causation opinions with regard to alleged defects in BSC's polypropylene mesh devices. I have previously reviewed the expert opinions of Dr. Barker under *Daubert*. *See Sanchez*, 2014 WL 4851989, at *5–10. The parties in this case assert the same arguments and to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. Additionally, as explained below, because I find Dr. Barker's opinions unreliable, I need not address his qualifications.

1. Mechanical Testing

First, BSC argues that Dr. Barker's opinions based on his mechanical testing should be excluded because they are unreliable and irrelevant. As explained below, because I exclude Dr. Barker's testing based on its methodological flaws, I need not address its relevance.

a. Protocols

BSC contends that Dr. Barker's testing methodology did not follow the published protocols he intended to replicate and eliminated key physiological conditions with no scientific basis. In *Sanchez*, I held as follows:

> Contrary to the published protocols, Dr. Barker did not conduct his testing in a saline bath, which was designed to help replicate the physiological environment of the human body. (*See* Barker Dep. [Docket 71-4], at 197:20–199:11).
>
> Dr. Barker's failure to conduct his testing in a saline bath is the fatal flaw in his methodology, particularly where Dr. Barker altered the protocols of peer-reviewed studies without a scientific basis for doing so. His only reasoning was that Georgia Tech denied him permission to submerge its equipment in saline, a "potentially corrosive" solution. (*Id.* at 197:20–198:21). The difference in the results obtained by Dr. Barker and by Drs. Shepherd and Moalli further demonstrate the unreliability of his method. Dr. Barker's tests revealed two to four times more relative elongation of the mesh than Drs. Shepherd and Moalli's tests. (*See* Shepherd, *supra*, at 617; Moalli, *supra*, at 662; Barker Report [Docket 71-1], at 21).
>
> Moreover, the use of a saline bath seems to be a particularly pertinent feature to the design of these mechanical tests. Drs. Shepherd and Moalli recognize that, ideally, tests should be done in vivo to learn about the mesh's behavior when inside of the human body. (*See* Shepherd, *supra*, at 619 (stating that "[f]urther research will need to correlate how those differences in biomechanical performance in the lab affect clinical outcomes"); Moalli, *supra*, at 663 (noting that "the next logical step to the current study is the implementation of rigorous in vivo studies to determine how the textile and tensile properties of polypropylene slings relate to tissue behavior, efficacy, patient morbidity, and patient satisfaction")). Dr. Barker seeks to opine about the effects of the mesh inside of the human body, yet Dr. Barker's study did not even attempt to replicate a physiological environment with the use of a saline bath. As a result, Dr. Barker's method is unreliable.

Id. at *7. Accordingly, I **ADOPT** my prior holding, as stated in *Sanchez*, and **FIND** Dr. Barker's methodology unreliable.

b. Sample Size

BSC contends that Dr. Barker's testing used insufficient sample sizes. In *Sanchez*, I held as follows:

> [Dr. Barker] tested one piece of Obtryx mesh and two pieces of Pinnacle mesh. (*See* Barker Report [Docket 71-1], at 22). Dr. Barker admits that having a sample size of one is "insufficient to perform statistical analysis." (Dr. Barker Dep. [Docket 71-4], at 233:17–234:5). As a result, it is difficult to predict whether his results were merely chance occurrences. Dr. Barker explains that he wanted additional materials and he would have conducted additional testing if they had been provided:
>
> > Q: In fact, a lot of the results that Dr. Moalli has published that are different than your results, don't you think you need to test another piece of Obtryx mesh to confirm or not confirm the results that you got based on your N equals 1?
> >
> > A: I would have liked to have been provided with materials, additional materials to do additional testing.
>
> (*Id*. at 233:2–12) (objections omitted). Dr. Barker similarly testified about his sample size of two for the Pinnacle:
>
> > Q: Now, with regard to the Pinnacle device, you had N equals 2, right?
> >
> > A: That's correct.
> >
> > Q: Okay. Did you do anything to determine the statistical confidence levels with regard to the testing that you performed on the two pieces of Pinnacle mesh?
> >
> > A: You cannot likewise perform a statistical test on an N of 2. A minimum is a minimum of 3.
>
> (*Id.* at 236:11–20). Dr. Barker's testing of merely one or two samples lacks reliability.

Id. at *7–8. Accordingly, I **ADOPT** my prior holding, as stated in *Sanchez*, and **FIND** Dr. Barker's methodology unreliable.

c. Peer-Review

BSC contends that Dr. Barker's testing has not been peer-reviewed and fails to meet peer-review standards. In *Sanchez*, I held as follows:

> Dr. Barker admits to this in his deposition testimony:

> Q: Would you agree with me that your testing that you performed on the Obtryx with an N of 1 wouldn't meet standards to be published in a peer-reviewed journal?
>
> A: I would.
>
> Q: And would you agree with me that your testing that you did on Pinnacle with an N of 2 wouldn't meet the standards to be published in a peer reviewed journal?
>
> A: I would agree.

(*Id.* at 301:20–302:5). Although peer review and publication is only one factor in the *Daubert* analysis and is not dispositive, Dr. Barker's admission sheds light on the flaws in his method.

Id. at *8. Accordingly, I **ADOPT** my prior holding, as stated in *Sanchez*, and **FIND** Dr. Barker's methodology unreliable.

d. In Vivo Environment

BSC contends that Dr. Barker' testing does not replicate in vivo conditions. In *Sanchez*, I held as follows:

> The mere fact that Dr. Barker's study was uniaxial does not alone render his methodology unreliable. Drs. Shepherd and Moalli's studies were also not precisely demonstrative of the forces in the female pelvic floor, and the authors recognize this limitation. (*See* Shepherd, *supra*, at 619 (stating that "[i]t is important to note that this testing was done ex vivo and in a single dimension"); Moalli, *supra*, at 662 (noting that, "[i]n this paper, we maintain that before studying the impact of slings on tissue behavior in vivo and clinical outcome, physicians should have a good working knowledge of the textile and biomechanical properties of different slings ex vivo").
>
> However, because Dr. Barker's method did not account for the multi-directional forces inside of the female pelvis, his opinions about the effect of the mesh once implanted in vivo are unreliable and do not survive *Daubert* scrutiny. Even Drs. Shepherd and Moalli note that their studies do not conclusively reveal the mesh's behavior in the human body. (*See* Shepherd, *supra*, at 619 (stating that "this experimental setup allows us to draw only preliminary conclusions about the various meshes"); Moalli, *supra*, at 663 (noting that "the behavior of these slings

> in vivo and after incorporation into host tissue may be inferred, but is not directly apparent from these studies")).

Id. at *8–9. Accordingly, I **ADOPT** my prior holding, as stated in *Sanchez*, and **FIND** Dr. Barker's methodology unreliable.

Therefore, Dr. Barker's opinions based on his mechanical testing are unreliable, and thus, **EXCLUDED**.

2. Mechanical Mismatch

BSC argues that Dr. Barker's opinions on mechanical mismatch are unreliable. In *Sanchez*, I held as follows:

> Dr. Barker is educated and experienced in the field of biocompatibility. (*See* Barker CV [Docket 89-4], at 1). He even says that, based on the elastic modulus he used, "it would be expected by anyone skilled in the art of biomechanical engineering that the relative movement between the Pinnacle . . . and their interacting tissues would be destructive to the tissue likely leading to inflammation and pain." (Barker Report [Docket 71-1], at 18). However, he based his elastic modulus calculations of the Pinnacle mesh on his methodologically flawed and unreliable testing. He also has not done "any cellular experiments to determine mismatch effects" or any specific testing to determine whether the material mismatch is significant between vaginal tissue and BSC mesh. (Barker Dep. [Docket 71-4], at 179:16–182:24). Furthermore, as explained above, Dr. Barker's testing does not replicate the forces and environment of the human body and, therefore, his opinions regarding the mesh's effects in vivo are unreliable.
>
> Focusing on these "principles and methodology," I conclude that Dr. Barker's opinions on the mechanical mismatch between the BSC meshes and vaginal tissue are unreliable and, thus, **EXCLUDED**. *Daubert*, 509 U.S. at 595.

Id. at *9. Accordingly, I **ADOPT** my prior ruling, as stated in *Sanchez*, and **EXCLUDE** this opinion.

In sum, BSC's motion with regard to Dr. Barker is **GRANTED**.

F. Motion to Exclude the Opinions and Testimony of Richard W. Trepeta, M.D.

In this case, the plaintiff offers Dr. Trepeta to testify as an expert witness on the general

pathology of vaginal mesh implantation. (*See generally* Trepeta Report [Docket 84-1]). Among other things, Dr. Trepeta is a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease. As part of his fellowship, he "establishes criteria and terminology for the diagnosis of vulvar and vaginal diseases." (*Id.* at 2). Dr. Trepeta also examines vaginal pathology samples through his private practice. (*See id.*). BSC moves to exclude Dr. Trepeta as an expert witness, raising two primary objections: (1) Dr. Trepeta is not qualified to opine on the properties of polypropylene mesh or the clinical responses to mesh implants; and (2) Dr. Trepeta's opinions are unreliable, irrelevant, and not helpful to the jury. (*See generally* BSC's Mem. in Supp. of Its Mot. to Exclude Richard W. Trepeta ("BSC's Mem. re: Trepeta") [Docket 85]). As further explained below, I **GRANT IN PART** and **DENY IN PART** BSC's Motion to Exclude Dr. Trepeta [Docket 84].

1. Dr. Trepeta's Qualifications

BSC begins by contending that Dr. Trepeta's background in pathology does not qualify him under Federal Rule of Evidence 702 to render the opinions he sets forth in his expert report on the properties of polypropylene and the human clinical response to polypropylene implants.

a. Properties of Polypropylene Mesh

Dr. Trepeta opines about mesh degradation, mesh contraction, and mesh migration. He states that "[d]egradation occurs as either fragmentation of the mesh or oxidation [of the mesh] release[s] chemical components from the mesh into surrounding tissues," and "[m]esh contraction and shrinkage cause the mesh to be significantly decreased in its physical size." (Trepeta Report [Docket 84-1], at 5). BSC asserts that Dr. Trepeta is not qualified to put forth these opinions because he is not a material scientist, biochemist, or biomedical engineer. (*See*

Trepeta Dep. [Docket 84-3], at 89:22–90:9). Furthermore, he has no training in polymer science or biomedical engineering and has not performed mechanical or chemical testing of mesh products. (*See id.* at 90:10–91:8).

In *Sanchez*, I assessed this argument and disagreed with BSC:

> In making [its] argument, however, BSC downplays Dr. Trepeta's knowledge, training, and experience as a clinical pathologist. In general, a clinical pathologist "will be knowledgeable in the areas of chemistry, hematology, microbiology, . . . serology, immunology, and other special laboratory studies." 33 Am. Jur. *Trials* 467, § 17 (1986); *see also* Coll. of Am. Pathologists, *CAP Fact Sheet*, http://www.cap.org (last visited Sept. 22, 2014) ("[Clinical pathologists] are involved in a broad range of disciplines, including surgical pathology, cytopathology, . . . clinical chemistry, microbiology, immunopathology, and hematology."). Dr. Trepeta's thirty years' experience as a clinical pathologist therefore demonstrates sufficient knowledge to provide expert testimony about the chemistry and surgical pathology of materials like transvaginal mesh. Moreover, Dr. Trepeta has knowledge of and experience with pelvic mesh explants in particular, having examined fifty explant samples over the past five years. (*See* Trepeta General Report [Docket 86–1], at 2). According to Dr. Trepeta, by examining the mesh explants under a microscope, he has witnessed the polypropylene's chemical changes. (*See* Trepeta Dep. [Docket 110–3], at 217:14–19). Given Dr. Trepeta's knowledge and experience as an anatomical and clinical pathologist, I **FIND** that he is qualified to testify about mesh degradation, mesh shrinkage, and mesh migration, and I therefore **DENY** BSC's motion in this respect.

2014 WL 4851989, at *20. I **ADOPT** this holding here.

b. The Human Clinical Response to Polypropylene Mesh

Dr. Trepeta also opines that the "human body's pathological response to implantation of polypropylene mesh as well as the inherent physical properties of the mesh cause permanent injuries resulting in distortion of the pelvic architecture, sexual dysfunction, persistent pain, scarring, and alteration of bowel and bladder function." (Trepeta Report [Docket84-1], at 6). BSC contends that Dr. Trepeta is not qualified to present this opinion because Dr. Trepeta does not treat patients for these conditions and has limited familiarity with the symptoms of SUI and

POP. In short, BSC argues that Dr. Trepeta is not a gynecologist, obstetrician, urogynecologist, or a surgeon, and as a result, Dr. Trepeta's opinions about the clinical response to mesh should be excluded.

In *Sanchez*, I addressed this argument and held:

> Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through "clinical and pathologic correlation." [(*See* Trepeta Dep. [Docket 86-3], at 11:10–14)]. Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic diagnosis about a patient. (*See id.*). Dr. Trepeta applied this pathologic process in reaching his conclusions about the human clinical responses to polypropylene vaginal mesh. He examined fifty pathology samples from mesh removals and opines that he observed injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Trepeta General Report [Docket 86-1], at 2). He also compared medical literature to these observations and concluded that his pathological findings "are well described in the published literature." (*Id.*). Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response. Therefore, I **DENY** BSC's motion on this point.

2014 WL 4851989, at *20 (footnote omitted). I **ADOPT** this holding here.

2. The Reliability and Relevance of Dr. Trepeta's Opinions

Next, BSC raises several objections to the reliability and relevancy of Dr. Trepeta's opinion testimony. I addressed each of these objections in *Sanchez* and consequently rely on *Sanchez* to explicate my conclusions here.

a. Reliability of Dr. Trepeta's Methodology in Formulating His Opinions

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion. First, Dr. Trepeta has studied over fifty mesh explant samples in his private practice. Dr. Trepeta received these samples from physicians about once a month over the past five years. (Trepeta Dep.

[Docket 84-3], at 63:1–5). He examined these samples under a microscope, identified any abnormalities, and concluded that the samples presented injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Trepeta Report [Docket 84-1], at 2). Second, Dr. Trepeta studied the medical literature on mesh implantation and determined that his pathological findings correspond with the published research on mesh erosion and exposure in the vaginal wall. (*Id.* at 2–3). Third, Dr. Trepeta reviewed twenty-four pathology reports that he received from the plaintiffs' counsel and ascertained that "the pathology reports of excised Boston Scientific Products . . . are consistent" with the acute, sub-acute, and chronic categories of the disease process. (*Id.* at 3–4).

As I held in *Sanchez:*

> BSC's strongest objection to Dr. Trepeta's methodology focuses on this third source of information. BSC argues that the twenty-four pathology reports were unreliable because: they were "hand-selected by Plaintiffs' counsel"; Dr. Trepeta only relied on seventeen of the twenty-four reports; and Dr. Trepeta did not review the medical records of any of the probed patients. (BSC's Mem. re: Trepeta [Docket 235], at 11–12). The plaintiffs respond that these pathology reports only supplemented Dr. Trepeta's opinion and that the main thrust of Dr. Trepeta's opinion comes from his review of fifty mesh explants over the past five years and from his study of medical literature. Moreover, the plaintiffs argue that BSC's chosen expert, Dr. Badylak, agreed that review of pathology reports of vaginal tissue taken from polypropylene explants is an accepted method for reaching a pathologic conclusion on tissue response to polypropylene. (*See* Pls.' Resp. in Opp. to Def.'s Mot. to Exclude Dr. Trepeta [Docket 110], at 13).
>
> The fact that each side's pathologist accepts this practice suggests that it is accepted by the general community of pathologists. *See Daubert*, 509 U.S. at 594 ("Widespread acceptance can be an important factor in ruling particular evidence admissible . . . ."). But Dr. Trepeta's review of the pathology reports still has a fatal deficiency in that it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. *See id.* (listing as a factor in evaluating an expert's opinion the "existence and maintenance of standards controlling the technique's operation"). The plaintiffs do not explain how or why they chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. *See id.* (stating that the "court ordinarily should consider the

> potential rate of error"). I confronted a similar situation in *Lewis, et al. v. Ethicon, Inc.* and excluded the expert opinion on hand-selected explant samples because "[t]here are no assurances that [plaintiffs' counsel] did not opportunistically choose samples while ignoring others that might have weakened or disproved [the expert's] theories." No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014). Here, I similarly have no way to ensure that the plaintiffs' counsel did not provide Dr. Trepeta with only those pathology reports that tended to strengthen, rather than refute, Dr. Trepeta's opinions. Accordingly, Dr. Trepeta's opinions derived from his review of the twenty-four pathology reports are **EXCLUDED.**

2014 WL 4851989, at *22. I **ADOPT** this holding, accepting Dr. Trepeta's opinions as reliable apart from those opinions based on his review of the twenty-four pathology reports.

b. Litigation Driven Opinions

BSC also argues Dr. Trepeta's opinions are unreliable because they are litigation-driven. Specifically, BSC asserts that Dr. Trepeta's "familiarity with the literature on polypropylene mesh comes only from his research and reading in connection with this litigation." (BSC's Mem. re: Trepeta [Docket 85], at 14). As in *Sanchez*, I disagree. Dr. Trepeta has largely based his opinions on his professional experience with mesh pathology samples examined during his practice. (Trepeta Report [Docket 84-1], at 2). In addition, he testified that he has "looked at mesh removed from the bodies of female vaginal walls under the microscope" and has seen degradation. (Trepeta Dep. [Docket 112-4], at 2:17:14–19). These activities occurred outside of this litigation. Thus, I **FIND** that Dr. Trepeta's opinions are not litigation-driven and **DENY** BSC's motion on this point.

In conclusion, Dr. Trepeta's general causation opinions satisfy *Daubert*, apart from his opinions based on the pathologic reports selected by the plaintiff's counsel for his review, which are **EXCLUDED.** Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Dr. Trepeta [Docket 84] is **GRANTED in part** and **DENIED in part**.

G. Motion to Exclude the Opinions and Testimony of Donald R. Ostergard, M.D.

As one of the five founders of the American Urogynecological Society, Dr. Ostergard is a seasoned obstetrician and gynecologist, having practiced in the field since 1970. He has also assumed several academic roles, most recently serving as a professor of obstetrics, gynecology, and women's health at the University of Louisville. The plaintiff offers Dr. Ostergard to testify as an expert witness on the properties of polypropylene; the design of the Obtryx sling; the regulatory process of the FDA, specifically with regard to product labeling; the motives and ethics of BSC; and specific causation regarding Ms. Hall. (*See generally* Ostergard Report [Docket 89-2]). BSC seeks to exclude these opinions under *Daubert*. I have previously reviewed Dr. Ostergard's expert testimony in *Tyree*. I rely on this analysis when evaluating Dr. Ostergard's opinions in this case.

1. Opinions on POP Devices

First, BSC objects to Dr. Ostergard's opinions on POP devices because such opinions are not relevant to this case, which does not concern a POP device and instead focus on the Obtryx, an SUI device. I agree that Dr. Ostergard's opinions on specific POP devices are not probative of any facts at issue here because the plaintiff has had no experience or interaction with POP devices. As a result, these opinions are **EXCLUDED**.[3]

2. Opinions on the Properties of Polypropylene Mesh

With respect to Dr. Ostergard's opinions regarding the properties of polypropylene, the Obtryx design, and the result of placing it into the body, BSC argues that Dr. Ostergard is not qualified to render these opinions and that the opinions do not satisfy *Daubert*'s reliability prong. I begin by finding that Dr. Ostergard possesses the expertise necessary to opine on these

[3] I note, however, that this ruling has no import on Dr. Ostergard's opinions regarding polypropylene mesh generally, which I separately evaluate below.

subjects, and I then conclude that these opinions have a reliable basis.

a. Qualifications

Dr. Ostergard offers opinions on the "defective" qualities of the polypropylene mesh used in the Obtryx sling, such as its "impurity" and its tendency to shrink, degrade, and oxidize. (Ostergard Report [Docket 89-2], ¶ 24). BSC maintains that Dr. Ostergard's clinical experience "does not qualify him to testify as to the specific chemical composition and attributes of polypropylene." (Mem. in Supp. re: Ostergard [Docket 90], at 15). In short, BSC argues that because Dr. Ostergard is not a biomaterials expert, he cannot testify about the properties of polypropylene. I can dispose of BSC's objection by referring back to my ruling on a prior *Daubert* challenge brought against Dr. Ostergard:

> It is difficult to deride Dr. Ostergard's qualifications generally. He has performed thousands of pelvic organ prolapse surgeries. He has used a variety of synthetic and biologic materials in pelvic reconstruction, including polypropylene mesh. He has extracted polypropylene mesh products from patients. He has treated them for mesh-related complications. He also performed preliminary theoretical work on a new pelvic mesh device for American Medical Systems.
>
> Dr. Ostergard has conducted scanning electron microscope imaging of mesh. He is also participating in an on-going study of its degradation characteristics in conjunction with his University of Louisville colleagues. Finally, Dr. Ostergard has published, in a peer reviewed setting, on a variety of synthetic and natural materials used in pelvic reconstruction surgery dating back to the 1980s. *I conclude that Dr. Ostergard's qualifications are sufficient to testify about polypropylene*.

(*Jones v. Bard, Inc., et al.*, No. 2:11-cv-00114 [Docket 391], at 6 (S.D. W. Va. Jan. 6, 2014) (footnote omitted) (emphasis added)).

Dr. Ostergard also opines about the "procedure design promoted by BSC." (Ostergard Report [Docket 89-2], ¶ 26). He concludes that insertion of the Obtryx through the vagina, a "contaminated surgical field," is "dangerous" and that the proximity of the Obtryx to various

pelvic organs and vessels creates a "risk of injury." (*Id.*). BSC argues that Dr. Ostergard has no experience in designing mesh products, and consequently, he lacks the qualifications necessary to opine on alleged design defects of the Obtryx. The plaintiff responds by pointing to Dr. Ostergard's extensive knowledge of the pelvic anatomy and pelvic reconstructive surgery. Furthermore, the plaintiff emphasizes Dr. Ostergard's published research on polypropylene materials, as well as his experience with the development of other mesh devices.

After reviewing Dr. Ostergard's curriculum vitae, I conclude that Dr. Ostergard is qualified to provide opinion testimony on the design of polypropylene slings. He has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products. As I explained in *Jones*, any challenge to his demonstrated expertise is "better suited for cross examination." (*Jones*, No. 2:11-cv-00114 [Docket 391], at 9).

In conclusion, I **FIND** that Dr. Ostergard is qualified to opine on the properties of polypropylene and the design of the Obtryx sling.

b. Reliability

Even if Dr. Ostergard has the requisite expertise to testify about product design, BSC contends that his opinions should be excluded as unreliable because (1) he has not supported them with testing; (2) the opinions arise from "selective citation of and improper extrapolation from scientific literature"; and (3) the opinions are not generally accepted in the medical community. (Mem. in Supp. re: Ostergard [Docket 90], at 8). I do not find these arguments persuasive. As an initial matter, general acceptance is merely one factor a court should consider in determining admissibility of expert testimony. *See Kumho Tire Co. v. Carmichael*, 526 U.S.

137, 151 (1999) ("[*Daubert*'s] list of factors was meant to be helpful, not definitive. Indeed, those factors do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged."). Here, although Dr. Ostergard's opinions conflict with the position statements of several urogynecological professional societies, he nevertheless finds support for his opinions in several peer-reviewed articles. (*See* Ostergard Report [Docket 89-2], at ¶ 24 (citing to various publications that corroborate his opinions on polypropylene mesh)). Consequently, that Dr. Ostergard belongs to the minority does not, in itself, render his opinion unreliable. Instead, I defer to the other *Daubert* factors and leave the profession's acceptance (or lack thereof) of Dr. Ostergard's opinions as a possible basis for impeachment at trial.

Further challenging the reliability of Dr. Ostergard's opinions, BSC contends that Dr. Ostergard has "conducted no testing on whether Boston Scientific mesh products in fact display the defects he describes." (Mem. in Supp. re: Ostergard [Docket 90], at 8). An expert, however, may support his opinions with resources other than the results of his scientific experimentation or testing. *See Daubert*, 509 U.S. at 592 ("Unlike an ordinary witness, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." (internal citations omitted)). In fact, "numerous courts have held that reliance on scientific test results prepared by others may constitute the type of evidence that is reasonably relied upon by experts." *Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed. Cir. 2008) (listing relevant case law). In *Jones*, I ruled that Dr. Ostergard's reliance on the analyses of others, when considered alongside his own peer-reviewed research, satisfied the reliability requirements of *Daubert*. (*Jones*, No. 2:11-cv-00114 [Docket 391], at 8). Revisiting Dr. Ostergard's list of publications on polypropylene mesh, (*see* Ostergard Curriculum Vitae [Docket 114-2], at 22–23), I again conclude that Dr. Ostergard's opinions have reliable support.

Finally, BSC asserts that Dr. Ostergard has "misinterpreted" the medical articles he relied on in reaching his opinions, and as a result, his opinions are unreliable. (Mem. in Supp. re: Ostergard [Docket 90], at 9). BSC's argument misplaces my role under *Daubert*. As the gatekeeper of expert testimony, I need not concern myself with the "correctness of the expert's conclusions" and should instead focus on the "soundness of his methodology." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("*Daubert II*"). As explained above, the review of other professionals' research can form a sound and reliable basis for an expert opinion. Here, Dr. Ostergard conducted a thorough review of others' medical research in establishing his opinions. (*See* Ex. 18 [Docket 114-18], at 63–71 (providing a list of medical literature that Dr. Ostergard considered in writing his expert report)). Whether Dr. Ostergard correctly interpreted this research has no bearing on the admissibility of his opinions. Accordingly, I **FIND** that Dr. Ostergard's opinions on the properties of polypropylene are reliable.

This holding, however, does not apply to Dr. Ostergard's opinion on the carcinogenicity of polypropylene. Although the plaintiff points to several studies connecting polypropylene to cancer, (*see* Pl.'s Opp. re: Ostergard [Docket 114], at 16 n.70), the plaintiff in this case has not claimed that the Obtryx caused cancer. Thus, "[t]he mention of cancer in the context of this case . . . would, at a minimum, offend Rule 702 and confuse the jury on a matter with scant probative value." (*Jones*, No. 2:11-cv-00114 [Docket 391], at 8, n.4). All of Dr. Ostergard's opinions on the carcinogenicity of polypropylene are **EXCLUDED**.

3. Opinions on FDA Regulatory Requirements and Product Labeling

Dr. Ostergard also comments on BSC's alleged noncompliance with FDA regulations, particularly as they relate to product labeling. BSC disputes Dr. Ostergard's qualifications to

opine on these matters, asserting that his "familiarity" with the warnings on mesh implant products does not rise to the level of expertise under *Daubert*. (Mem. in Supp. re: Ostergard [Docket 90], at 13–14). The plaintiff, on the other hand, contends that Dr. Ostergard's experience as a urogynecologist surgeon makes him "extremely well suited" to describe the information that BSC should have included on the directions for use and brochure for the Obtryx sling. (Pl.'s Opp. re: Ostergard [Docket 114], at 18). Moreover, Dr. Ostergard has "taken a course on the FDA process" and reviewed internal BSC documents that, in the plaintiff's view, give him the knowledge of the regulatory process needed to support his opinions. (*Id.* at 17–18).

Without more, however, Dr. Ostergard's distinguished career as a urogynecologist cannot uphold his opinions on product warnings and FDA compliance. First, Dr. Ostergard admitted that he is "not an expert in FDA regulations." (Ostergard Dep. [Docket 89-4], at 395:23–25). Second, his understanding of medical device warnings does not exceed the knowledge of physicians in general. That is, he has never drafted a device warning, and he only knows the "information that would be useful to the physician and his counseling of patients." (*Id.* at 402:15, 20–23).[4] This minimal experience with medical device warnings and FDA regulations does not satisfy the "knowledge, skill, experience, training, or education" required under Rule 702. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) ("Despite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process."). Accordingly, I **EXCLUDE** Dr. Ostergard's opinion testimony as it relates to product labels, the Obtryx's directions for use, and

[4] The fact that Dr. Ostergard took a single online course on the FDA regulatory process—a course that is freely available to the public—does not alter my conclusion that Dr. Ostergard lacks the qualifications necessary to opine about BSC's compliance with FDA regulations.

FDA compliance.[5]

4. Specific Causation

Finally, BSC argues that the court should exclude Dr. Ostergard's specific causation opinions regarding Ms. Hall because (1) the opinions derive from Dr. Ostergard's unreliable general causation opinions, and (2) Dr. Ostergard failed to connect his general causation opinions specifically to Ms. Hall. The first argument fails. As indicated above, Dr. Ostergard may testify from a causation perspective on polypropylene and product design in the areas indicated. Thus, his specific causation testimony is not excludable for lack of a general causation predicate.

BSC's second argument is likewise unpersuasive. I recognize that there is somewhat of a loose connection between Dr. Ostergard's general causation opinions and specific causation opinions—he explains the general characteristics of polypropylene by using the term "degradation" but comments on Ms. Hall's symptoms by using the word "erosion." (*Compare* Ostergard Report [Docket 89-2], ¶ 24, *with id.* ¶ 23). This disparity alone, however, does not warrant the exclusion of Dr. Ostergard's specific causation opinion, given that he appears to have used reliable methodology in reaching it. He thoroughly reviewed Ms. Hall's medical records and the depositions of her treating physicians, and then he conducted a differential diagnosis of her symptoms. (*See* Ostergard Dep. [Docket 114-6], at 30:12–31:23 ("[H]aving a differential diagnosis in hand, I am then able to look through that and from the standpoint of medical probabilities make some decisions as to what is going on with this particular patient . . . .")).

[5] Having excluded Dr. Ostergard's FDA opinions for insufficient expertise, I do not need to consider *Daubert*'s follow-up question of whether these opinions would be helpful to the jury. My ruling in *Sanchez, et al. v. Boston Scientific Corp.*, however, provides an analysis on the issue that I could easily apply here. *See* No. 2:12-cv-05762, 2014 WL 4851989, at *35 (S.D. W. Va. Sept. 29, 2014) ("Given that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations.").

Seeing no objection to this methodology, I **FIND** that Dr. Ostergard's specific causation opinion meets the standards of *Daubert*. *See, e.g.*, *Tyree*, 2014 WL 5320566 at *53 (finding that a physician's consideration of the patient's medical history and test results in the light of applicable publications "is enough to get through *Daubert*'s gate").

In sum, BSC's Motion to Exclude the Opinions and Testimony of Dr. Ostergard [Docket 89], is **GRANTED in part** and **DENIED in part**.

H. Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. and Samuel P. Gido, Ph.D.

BSC seeks to exclude the expert opinions of Jimmy W. Mays, Ph.D. and Samuel P. Gido, Ph.D. Drs. Mays and Gido are chemistry professors who offer opinions on the allegedly defective nature of the Obtryx based upon their review of scientific literature and their own chemical testing. I have previously reviewed the expert opinions of Drs. Mays and Gido under *Daubert*. *See Sanchez*, 2014 WL 4851989, at *24–30; *see also Tyree*, 2014 WL 5320566 at *19–24. The parties in this case assert the same arguments and to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material.

1. Chemical and Microscopic Testing

First, BSC argues that Drs. Mays and Gido's opinions based on their chemical and microscopic testing should be excluded because they are unreliable. In *Sanchez*, I ruled as follows:

> *[a.]Lack of Control for Error or Bias*
>
> Although plaintiffs' counsel selected the samples, counsel explained that these were the only Pinnacle and Obtryx samples available in the Steelgate repository. Therefore, unlike *Lewis*, where Dr. Klinge did not indicate whether the meshes examined constituted a large sample size of the repository's collection, here, these were the only samples available for testing. Furthermore, certain samples were not tested because they did not have enough mesh, not because of bias. Despite

the differences in these two cases, the fact that Drs. Mays and Gido's sample was not very large or randomly selected affects the reliability of their testing. *See Edwards v. Ethicon*, No. 2:12-cv-09972, 2014 WL 3361923, at *39 (S.D. W. Va. July 8, 2014) (excluding plaintiffs' expert's analysis of pelvic mesh explants generally). Drs. Mays and Gido "[have] given no explanation as to whether [theirs] is a representative sample size . . . . Therefore I have no information as to the potential rate of error inherent in [their] observations." *Lewis*, 2014 WL 186872, at *8. Additionally, Drs. Mays and Gido have no knowledge of how the material they examined was explanted or how it was preserved and handled before reaching their lab. (Mays Dep. [Docket 99-1], at 304–05).

Dr. Gido conducted EDS testing to differentiate between polypropylene fibers and biological material. In their report, Drs. Mays and Gido state that "the presence or absence (or near absence) of nitrogen as detected by EDS is the key discriminator between clean polypropylene fibers from which valid conclusions can be drawn or biomaterial covered fiber from which conclusions are less straightforward." (Mays & Gido Report [Docket 98-1], at 31). At his deposition, Dr. Gido acknowledged that on a relatively clean sample "there might be a little blip of nitrogen [in the EDS] and the question is, you know, is that nitrogen statistically significant." (Gido Dep. [Docket 99-2], at 154). However, Dr. Gido never determined the significance of potential "blips," although the data was available. (*Id.* ("I did not do that analysis, although the data is all there, and if that analysis needs to be done, I would contend it is not a new opinion.")).

Similarly, in their report, Drs. Mays and Gido state that "[w]e need to base our conclusions related to fiber degradation on clean polypropylene fibers and make sure we are not looking at biological films coating the fibers." (Mays & Gido Report [Docket 98-1], at 31). However, both Dr. Mays and Dr. Gido admit in their depositions that their inconsistent bleach treating techniques may have failed to remove all biologic material from the test samples. (*See* Mays Dep. [Docket 99-1], at 208; *see also* Gido Dep. [Docket 99-2], at 165). When asked explicitly whether they completed a statistical analysis or calculated a rate of error based on their tests, Dr. Gido admitted they did not. (Gido Dep. [Docket 99-2], at 154–55).

The key *Daubert* inquiry is "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Daubert II*, 43 F.3d at 1317. The small sample size and Drs. Mays and Gido's failure to determine the statistical significance of their results call into the question the reliability of their methods. Although *Daubert* is a flexible inquiry, these facts weigh heavily against the reliability of their opinions.

[b.]Failure to Establish or Adhere to Testing Protocol

First and most simply, Dr. Mays states that "SEM is a very common tool," but

> when asked if he prepared any written methodology before completing the SEM testing, he admits that he did not. (Mays Dep. [Docket 99-1], at 162). In addition, Dr. Mays and Dr. Gido both reference Dr. Gido's completely subjective cracking standard he came up with for purposes of their testing. Dr. Mays admits that the standard cannot be found in any published material, and Dr. Gido admits that he has never created or used a cracking standard before. (*See id.* at 18; *see also* Gido Dep. [Docket 99-2], at 161).
>
> Expanding on the brief discussion above, while the samples were with Dr. Gido for testing, Dr. Mays asked Dr. Gido to try bleach cleaning one of the explants to see if it was effective. (Gido Dep. [Docket 99-2], at 167). Dr. Gido used a 6% bleach concentration on explanted sample 11. (*See id.* at 193; Mays & Gido Addendum Report [Docket 111-5], at 2). In comparison, Dr. Mays used a 7.8% concentration to clean the explants and controls before testing. (*See* Mays & Gido Report [Docket 98-1], at 33). The bleach treatments were clearly inconsistent. Additionally, Drs. Mays and Gido have no explanation as to why a discussion of this testing was "mistakenly" omitted from their original report. (Mays Dep. [Docket 99-1], at 202).
>
> Another mistake occurred after Dr. Gido returned the samples, and he discovered that he failed to conduct an EDS test on one of them, which he attributed to a mere oversight. (Gido Dep. [99-2], at 214–15). Finally, Dr. Mays conducted TGA testing on the explants to determine what additives were in the mesh, but for some reason did not include the results in their expert report. (*Compare* Mays Dep. [Docket 99-1], at 50, *with* Mays & Gido Report [Docket 98-1]).
>
> Although Drs. Mays and Gido performed tests that are supported by the literature, the haphazard application of these tests, errors, and changes to their report lead to the conclusion that their methodology is unreliable. Vigorous adherence to protocols and controls are the hallmarks of "good science." *See Black v. Rhone-Poulenc, Inc.*, 19 F. Supp. 2d 592, 603 (S.D. W. Va. 1998). Accordingly, I **FIND** that the testing performed by Drs. Mays and Gido is unreliable, and therefore, **EXCLUDED**.

Sanchez, 2014 WL 4851989, at *26–28. Accordingly, I **ADOPT** my prior ruling, as stated in *Sanchez*, and **FIND** that the testing performed by Drs. Mays and Gido is unreliable, and thus, **EXCLUDED**.

2. Opinions Not Based on Testing

BSC argues that Drs. Mays and Gido's opinions are unreliable because they are litigation driven, not scientific, and not fair and balanced. In *Tyree*, I held as follows:

> While BSC argues that Drs. Mays and Gido's unreliable testing should be excluded entirely, the plaintiffs respond by explaining that the testing "merely confirmed what [Drs. Mays and Gido] have long known because of their training, experience, and peer-reviewed published scientific literature." (Pls.' Mem. in Opp'n to Def.'s Mot. to Exclude Test. of Pls.' Expert ("Pls.' Mem. re: Mays & Gido") [Docket 272], at 4). The plaintiffs contend that both the expert report and depositions support this explanation; however, they conveniently choose to cite only Dr. Mays's deposition in support of their proposition. (*See id.* at 4–5; *see also* Mays Dep. [Docket 272-5], at 65 ("I believe all of my conclusions are ones that one could reach simply by looking at published literature on polypropylene that's been implanted into the human body combined with the knowledge of chemistry and polymer science and the behavior of polymeric materials."); *id.* at 140 ("So my opinion is based on my experience as a scientist, as a chemist. It's based on all the literature we looked at. It's based also on the testing that we did in this report."); *id.* at 260 ("My opinion in this case, and it was my opinion before I got involved in this case, is that polypropylene is so fundamentally susceptible to oxidative degradation that it's a poor choice for permanent implant where there's going to be tissue ingrowth.")).
>
> The plaintiffs fail to point out or cite Dr. Gido's deposition testimony, which takes the opposite position. Dr. Gido explicitly states that "we're making this statement based on our own study and our own results. We're not getting it from the literature." (Gido Dep. [Docket 221-3], at 233). While Dr. Mays describes the testing as "confirmatory," Dr. Gido highlights the fact that he completed the testing first and then "got into the literature." (Mays Dep. [Docket 272-5], at 65; Gido Dep. [Docket 221-3], at 50). Dr. Gido admits that he had not reached his opinions before testing and emphasizes how important the data was in drafting his portions of the report. (*See* Gido Dep. [Docket 221-3], at 51 ("I would suspect the same – you know, I would probably conclude that there would likely be a problem with polypropylene, but I would not be as sure of it as I am having seen data that I took with my own hands and seen Dr. Mays's data.")). Based on the depositions, Drs. Mays and Gido clearly have different opinions regarding the nature and influence of the testing they performed.
>
> I have determined that Drs. Mays and Gido's testing was unreliable, and Dr. Gido states that his opinions are based solely on the testing. Accordingly, I **FIND** that Dr. Gido's opinions are **EXCLUDED**. However, as discussed more fully below, because Dr. Mays indicates that he relied primarily on other scientific sources, I **FIND** that Dr. Mays is permitted to testify generally about polypropylene degradation based on his experience and review of the literature.

Tyree, 2014 WL 5320566 at *22–23 (footnote omitted). Accordingly, I **ADOPT** my prior ruling, as stated in *Tyree* and **EXCLUDE** Dr. Gido's opinions. I **FIND** that Dr. Mays is permitted to

testify generally about polypropylene degradation based on his experience and review of the literature.

I. Motion to Exclude the Testimony of Dr. Mark Slack

BSC seeks to exclude the expert opinions offered by Mark Slack, M.D. Dr. Slack is a consultant gynecologist and practicing urogynecologist in the United Kingdom. I have previously reviewed the expert opinions of Dr. Slack under *Daubert*. *See Eghnayem*, 2014 WL 5461991 at *32–34. The parties in this case assert the same arguments and to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. In *Eghnayem*, I held as follows:

> Much of Dr. Slack's export report is a narrative review of corporate documents and his opinions are riddled with improper testimony regarding BSC's state of mind and legal conclusions. (*See, e.g.*, Slack Report [Docket 99-1], at 13 ("Boston Scientific had an obligation to critically evaluate all of the potential complications and their consequences, in order to adequately warn physicians and patients. Boston Scientific did not satisfy their obligation by failing to study the grave consequences of attempting to treat mesh complications, and did not recognize or admit that the devices might introduce too much risk and should be studied before being marketed."); *id.* at 16 ("Boston Scientific recognized the problems created by not having clinical data supporting the use of its products."); *id.* at 19 ("In March 2007, the Boston Scientific clinical affairs department knew that if a woman suffered erosion or exposure of mesh the consequences could be severe including the need for follow up invasive surgery. This potential significant risk, with the root cause being the mesh itself, was foreseen by Boston Scientific before marketing a single Pinnacle device."); *id.* at 20 ("It appears that as early as 2003, Boston Scientific knew that there could be problems with the polypropylene mesh."); *id.* at 21 ("Boston Scientific was aware of the significant role physician training has with respect to patient safety."); *id.* at 22 ("Boston Scientific knew prior to the time these products were placed on the open market that surgeon technique could impact surgical outcome."); *id.* at 23 ("It was Boston Scientific's goal to create a standardized, reproducible surgical technique."). In fact, an entire section of Dr. Slack's report is about how BSC possessed the same knowledge as the scientific community regarding the safety and efficacy of pelvic floor products before introducing their product into the market. (*Id.* at 10–12).
>
> Dr. Slack also opines on what course of action BSC should have taken; however, the majority of Dr. Slack's opinion simply recites what BSC did or did not do. *See*

> *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) ("An expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based on the record of evidence."). As I previously discussed, expert opinions on BSC's knowledge, state of mind, and legal conclusions are not appropriate subjects of expert testimony. Therefore, these opinions are **EXCLUDED**, and BSC's Motion to Exclude the Testimony of Dr. Slack [Docket 98] is **GRANTED**.

Id. Accordingly, I **ADOPT** my prior ruling, as stated in *Eghnayem*, and **GRANT** BSC's motion with regard to Dr. Slack.[6]

J. Motion to Exclude the Testimony of Dr. Peggy Pence

Dr. Pence works as a clinical and regulatory consultant, providing "advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the [FDA]." (Pence Report [Docket 123-1], at 1). During her career, she has accumulated knowledge about and experience with the testing requirements for medical devices; the development and content of product labeling; and the procedures necessary to comply with regulatory and industry standards, including those set forth by the FDA. (*See id.* at 1–4). In this matter, Dr. Pence offers four opinions: (1) BSC did not conduct adequate testing of the Obtryx product prior to placing them on the market; (2) the Obtryx product was inadequately labeled; (3) patients could not adequately consent to the surgical implantation of the Obtryx due to the misbranding of these products; and (4) BSC failed to meet the postmarket vigilance standard of care for their products, leading to further misbranding. BSC seeks to exclude Dr. Pence's testimony in its entirety.

I have previously reviewed the opinion testimony of Dr. Pence under *Daubert*. *See Sanchez*, 2014 WL 4851989, at *32–36. The reasoning in *Sanchez* substantially reflects the

[6] Because Dr. Slack's impermissible state of mind opinions permeate his entire expert report, I need not address the remainder of BSC's specific objections based on reliability.

court's view of this issue as presented here. To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. Therefore, I **ADOPT** my prior ruling on Dr. Pence as follows and thereby **GRANT in part** and **DENY in part** her expert opinion.

1. Dr. Pence's Qualifications

I first address BSC's argument that this court should exclude Dr. Pence's opinions because she lacks the qualifications necessary to make them. BSC maintains that Dr. Pence's work as a researcher and consultant does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. In BSC's view, without a medical degree and without experience in the development of polypropylene mesh, Dr. Pence's opinions on BSC's medical devices cannot withstand *Daubert.*

In *Sanchez*, I ruled as follows, and I **ADOPT** that ruling here:

> The absence of a medical degree on Dr. Pence's curriculum vitae does not call into doubt Dr. Pence's demonstrated knowledge about and experience with medical devices like the [Obtryx]. Dr. Pence has over forty years of experience in the research and development of medical devices. (Pence Report [Docket 118-1], at 1). Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, . . . I **FIND** that Dr. Pence is qualified to render the opinions set forth in her expert report, including her opinions about the safety and efficacy of mesh products and the sufficiency of BSC's product branding.

Id. at *33.

2. Dr. Pence's Opinions on Appropriate Pre-Market Testing

Having found that Dr. Pence is qualified to offer these opinions, I next address whether her opinions are relevant and reliable. In her report, Dr. Pence opines:

> BSC should have performed adequate preclinical and clinical testing of the Obtryx Sling and Pinnacle PFR Kits prior to marketing to ensure the devices were reasonably safe for permanent implantation. By its failure to do so, BSC fell below the standard of care required of a reasonably prudent medical device

manufacturer.

(Pence Report [Docket 123-1], at 44). In reaching this conclusion, Dr. Pence considered the risks associated with polypropylene mesh (*id.* at 31–36); the statements in Material Safety Data Sheets provided by the polypropylene supplier in 2004 indicating that polypropylene should not be used for permanent implantation in the human body (*id.* at 36–40); and the developmental history of BSC products (*id.* at 41–43).

In *Lewis, et al. v. Ethicon*, Dr. Pence gave a similar opinion. No. 2:12-cv-4301, 2014 WL 186872, at *18–19 (S.D. W. Va. Jan. 15, 2014). She opined that the defendant did not conduct the required investigative tests on the specific risks of a transvaginal mesh product, but she failed to support this opinion with any authority suggesting that the performance of such tests was needed. *Id.* at *18. Without a reliable foundation, I excluded Dr. Pence's opinion as unreliable. *Id.* at *19. Here, BSC argues that Dr. Pence's expert report should again be excluded as unreliable because it fails to point to any authority requiring BSC to perform the tests that Dr. Pence believes should have been conducted. The plaintiff counters that Dr. Pence has revised her report to fix the deficiencies identified in *Lewis*. This time around, the plaintiff argues, Dr. Pence has "clearly demonstrated that her methodology and opinions were not based upon her 'professional opinion' alone" and instead arose from her review of a "voluminous amount of peer-reviewed scientific articles, data, government codes and regulation, deposition testimony provided in this litigation, and internal documents received from BSC." (Pl.'s Resp. in Opp. to Def.'s Mot. to Exclude Dr. Peggy Pence [Docket 135], at 5).

In *Sanchez,* I agreed with the plaintiffs and concluded that

> Dr. Pence's bolstered expert report [Docket 118-1] has tempered my previous concerns about the reliability of her opinion on this issue. Dr. Pence has cited to multiple sources that stress the importance of running clinical trials before

> incorporating mesh materials into a surgical product. For instance, she describes a 2006 study conducted by the French National Authority for Health ("HAS"), in which it evaluated the safety and efficacy of vaginally implanted mesh for the treatment of genital prolapse. (Pence Report [Docket 118-1], at 9). HAS concluded that "the use of mesh implants for transvaginal correction of genital prolapse remained a matter of clinical research" and recommended prospective studies on the anatomical and functional outcomes of mesh implantation, the mid- to long-term effects, possible adverse events like erosion, and the management of erosions and retractions. (*Id.* at 10). Dr. Pence also discusses the recommendations of the National Institute for Health and Care Excellence, which include the warning that transvaginal mesh repair "should be used with special arrangements for clinical governance, consent and audit or research." (*Id.* at 43).
>
> In contrast with *Lewis*, Dr. Pence's opinion in this case is backed by authoritative studies that recommend the performance of clinical trials and long-term follow-ups before using polypropylene mesh. Thus, her opinion on the inadequacy of BSC's pre-market testing is more than a bare declaration of her professional opinion. Accordingly, I **FIND** that Dr. Pence's methodology is reliable under *Daubert* and **DENY** BSC's motion with respect to this opinion.

Sanchez, 2014 WL 4851989, at *34. I **ADOPT** this ruling here.

3. Dr. Pence's Opinions on the Adequacy of BSC's Product Labels

Dr. Pence proffers two opinions regarding the labeling of the Obtryx. First, she states that "BSC marketed [these products] without adequate instructions for use throughout the life of these products . . . , in particular, without adequate warnings, precautions, and information about the likelihood and extent of potential risks." (Pence Report [Docket 123-1], at 62). Second, she states that "patients implanted with the Obtryx Sling or Pinnacle mesh were prevented from . . . giving true informed consent as a result of BSC's inadequate professional and patient labeling." (*Id.* at 63). She then offers a list of warnings and risks that she believes should have been included in the products' instructions for use ("IFU") and patient brochures.

BSC asserts that these opinions should be excluded because they relate to BSC's deviation from the branding requirements of the Food, Drug, and Cosmetic Act ("FDCA"), which is irrelevant in this case and consequently unhelpful to the jury. The plaintiff agrees that

whether BSC violated the FDCA is not relevant and that Dr. Pence will not offer an opinion on that issue. The plaintiff stresses, however, that Dr. Pence's testimony about labeling is relevant to the plaintiff's failure-to-warn claim. This court dismissed the plaintiff's failure-to-warn claim at summary judgment, (Mem. Op. & Order [Docket 157], at 15), and as a result, Dr. Pence's testimony on labeling is irrelevant and inadmissible under *Daubert*.

4. Opinion on Postmarket Vigilance

In her last opinion, Dr. Pence proffers that BSC "deviated from the standard of care by its failure to report to [the] FDA a number of adverse events that met the criteria for Medical Device Reporting, rendering the Obtryx and Pinnacle devices misbranded as a result of failure to furnish information requested under Section 519 of the FDCA." (*See* Pence Report [Docket 123-1], at 83). BSC argues that whether BSC "reported certain adverse events to the FDA is not helpful to the jury" in determining whether BSC provided adequate warnings or whether its products were defective. (*See* BSC's Mem. in Supp. of Its Mot. to Exclude Dr. Pence [Docket 123], at 9).

> For the reasons explained in *Sanchez*, I agree with BSC.
>
> > Dr. Pence cites to FDA public health notifications, the FDA's corporate warning letter to BSC, and the FDCA's Medical Device Reporting regulations. Contrary to the plaintiffs' assertions, however, the FDCA's reporting requirements and BSC's alleged violation of them have minimal relevance. First, the plaintiffs have not brought any claims concerning the FDCA. Second, even if an explanation of BSC–FDA communications could shed light on the state law claims at issue, testimony on whether or not BSC complied with the FDCA would constitute an impermissible legal conclusion rather than an expert opinion. And finally, . . . opinion testimony on the labyrinth of reporting regulations within the FDCA has little probative value compared to the substantial risk of jury confusion, particularly when both parties agree that "whether, how, and when BSC communicated safety information to the FDA is irrelevant." (*See* Pls.' Resp. re: Pence [Docket 122], at 17). Accordingly, . . . I **EXCLUDE** Dr. Pence's opinions on postmarket vigilance.

Sanchez, 2014 WL 4851989, at *36.

In conclusion, Dr. Pence can testify on pre-market testing, but her other opinions on the adequacy of product labels and the reporting of adverse events to the FDA are **EXCLUDED.** As such, BSC's Motion to Exclude Peggy Pence [Docket 122] is **GRANTED IN PART** and **DENIED IN PART.**

IV. The Plaintiff's *Daubert* Motions

In this case, the plaintiff seeks to limit or exclude the expert opinions of Patrick Culligan, M.D., Peter Finamore, M.D., and Christine Brauer, Ph.D.

A. Motion to Limit the Opinions and Testimony of Patrick Culligan, M.D.

The plaintiff seeks to limit the expert opinions of Patrick Culligan, M.D. Dr. Culligan is a urogynecologist who offers opinions on the physical properties of polypropylene, the design of their Obtryx, the DFU for the Obtryx, and the Obtryx patient brochure. I have previously reviewed the expert opinions of Dr. Culligan under *Daubert*. *See Tyree*, 2014 WL 5320566 at *65–69. The parties in this case assert the same arguments and to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material.

1. Physical Properties

First, the plaintiff argues that Dr. Culligan may not offer expert opinions regarding the physical properties of polypropylene.

a. Qualifications

The plaintiff contends that Dr. Culligan lacks the necessary knowledge, skill, experience, training, or education to testify regarding the physical properties of polypropylene. In *Tyree*, I held as follows:

> Dr. Culligan is an accomplished urogynecologist. (*See id.* at Ex. A (Dr. Culligan's curriculum vitae)). He has experience treating women for POP and urinary incontinence, (*see id.* at 1), and performing mesh revision surgeries once or twice

a month for approximately the last ten years. (*See* Culligan Dep. [Docket 277-3], at 58:15–21). Dr. Culligan has served on university faculties, published peer-reviewed articles concerning mesh and sling procedures, and served as a reviewer for scientific journals. (*See* Culligan Report [Docket 233-2], at 2–8). He also relied upon scientific literature in forming his opinions. (*See id.* at 1–16, Ex. B). In fact, the "[p]laintiffs do not challenge Dr. Culligan's qualifications as a urogynecologist." (*See* Pls.' Mem. of Law in Supp. of Their Mot. to Limit the Ops. & Test. of Patrick Culligan, M.D. ("Pls.' Mem. re: Culligan") [Docket 234], at 5). Instead, the plaintiffs challenge his qualifications to opine as to the properties of polypropylene.

Dr. Culligan testified that he is not an expert in materials:

Q: And does the pore size change after implantation?

A: Well, we're beginning to get into a line of questioning that would require me to be more of a materials expert, which I'm not.

* * *

Q: Do you know if the Obtryx sling is heated in any fashion when it's manufactured?

A: I – I don't know the specifics of the manufacturing process for these. I'm not a materials or manufacturing expert.

Q: And that's a good point. Maybe I should have asked that at the beginning, could have saved some time. Are you an expert in biomaterials?

A: No, I'm not an expert in biomaterials.

(Culligan Dep. [Docket 233-3 & 233-4], at 57:9–15, 325:9–20) (objections omitted). However, this testimony is not dispositive. *See Huskey, et al., v. Ethicon, Inc., et al.*, No. 2:12-cv-05201, 2014 WL 3362264, at *36 (finding Dr. Johnson qualified to opine about polypropylene notwithstanding his deposition testimony "Q: Okay. You're not a biomaterials expert, are you? A: Um, I'm a clinical medical expert."). I have previously found certain medical doctors qualified to opine as to polypropylene. *See Jones v. Bard, Inc., et al.*, No. 2:11-cv-00114, [Docket 391], at 6–9 (finding Dr. Ostergard qualified to opine as to polypropylene and product design); *Huskey*. 2014 WL 3362264, at *35–37 (finding Dr. Johnson qualified to opine as to mesh degradation)). Dr. Culligan has similar types of experience as these prior experts. *See Jones*, No. 2:11-cv-00114, [Docket 391], at 1, 6–7 (noting Dr. Ostergard's performance of thousands of POP surgeries, SEM imaging of mesh, participation in an ongoing degradation study, and practice of 45 years); *Huskey*, 2014 WL 3362264, at *36 (noting Dr.

> Johnson's experience implanting at least 750 TVT and TVT-O devices, performance of 25–30 polypropylene sling revisions, and research on urinary incontinence treatments).

Id. at *65–66. Accordingly, I **ADOPT** my prior ruling, as stated in *Tyree*, and **FIND** that Dr. Culligan is qualified to opine on the physical properties of polypropylene mesh.

b. Reliability

The plaintiff also contends that Dr. Culligan's opinions related to the physical properties of polypropylene are not supported by a reliable foundation. In *Tyree*, I ruled as follows:

> Although Dr. Culligan is qualified to testify about polypropylene, his method is unreliable. In *Huskey*, I found that "drawing on clinical experience and a review of relevant literature is a sufficiently reliable method of forming" a similar opinion regarding degradation. *See Huskey*, 2014 WL 3362264, at *36. However, even if Dr. Culligan considered both scientific literature and his experience, his deposition testimony reveals flaws in his method:
>
> Q: And does that pore size change after implantation?
>
> A: Well, we're beginning to get into a line of questioning that would require me to be more of a materials expert, which I'm not.
>
> Q: Okay.
>
> A: So – but I can give you my clinical opinion.
>
> Q: Go ahead.
>
> A: That, no I don't believe the pore size changes from any of my clinical experience with the products.
>
> Q: And what do you base that opinion on?
>
> A: My only experience with your question would have to do with removing products and just examining them grossly whenever I've had to do that.
>
> (Culligan Dep. [Docket 233-3 & 233-4], at 57:9–58:4) (objections omitted). Dr. Culligan's opinions regarding polypropylene are general and do not relate to a particular plaintiff. Basing an opinion on "gross[ ]" examinations of products "whenever [he] had to do that" is not a reliable scientific methodology to reach these generalized conclusions. (*See id.* at 58:1–4). Dr. Culligan elaborates further:

> Q: . . . [Y]ou said you grossly examined some mesh that you've explanted. Have you ever tried to determine in any measurement form whether the shape or size of the mesh has changed significantly?
>
> A: No. It wouldn't be relevant to what I'm talking about because if I remove part of a piece of mesh, I'm removing part of that mesh and I wouldn't have any way to measure that against how that specific part that I removed was sized, you know, when it was placed. It's – it's impossible to make a before and after comparison like that.
>
> (*Id.* at 428:16–429:6). Dr. Culligan fails to provide a sound basis for his opinions. His method is unreliable, and, therefore, his opinions as to the properties of polypropylene are **EXCLUDED**.

Id. at *66–67. Accordingly, I **ADOPT** my prior ruling, as stated in *Tyree*, and **EXCLUDE** these opinions.

2. Design

Next, the plaintiff argues that Dr. Culligan may not offer expert opinions regarding the design of transvaginal mesh, particularly, the Obtryx. In *Tyree*, I held as follows:

> First, the plaintiffs argue that Dr. Culligan lacks qualifications to opine as to the design of transvaginal mesh. In support, the plaintiffs point to deposition testimony of Dr. Culligan, where he admits that he is not an expert in design and where he is unable to answer questions concerning pore size, contraction, and the word "detanged," which the plaintiffs contend are "important design components." (Pls.' Mem. re: Culligan [Docket 234], at 8–9).
>
> Dr. Culligan states that he is no expert in product design:
>
> Q: Okay. Are you an expert in the design of slings?
>
> A: I'm not sure quite how to answer that. I have never designed one that was manufactured, but I certainly have preferences. And as a surgeon I am certainly an expert on how to implement designs. So it's – it's – I hope you understand there's a – sort of an overlap there.
>
> Q: Let me see if I can make it easier. You're not an expert in determining the appropriate pore size, for example, for slings, are you?
>
> A: Well, as I mentioned earlier today, there tends to be a sort of a

> classification system for the mesh products. And the mesh products that are available tend to fall within the pore size that's thought of as the Type I mesh material. So I would not be in a position to determine the pore size of a sling. I don't manufacture slings.
>
> Q: And that goes back to the fact that you're not an expert in biomaterials; correct?
>
> A: Correct. I'm not a biomedical engineer.
>
> (Culligan Dep. [Docket 233-3 & 233-4], at 326:17–327:24) (objections omitted). In *Jones*, I found Dr. Ostergard, also a urogynecologist, qualified to testify about product design based on his knowledge and experience. *See Jones*, No. 2:11-cv-00114, [Docket 391], at 8–9. However, Dr. Ostergard had performed sling product design work "namely, a polytetrafluoroethylene suburethral sling in the 1980s, along with . . . design theory work for AMS[.]" *Id.* at 9. Here, Dr. Culligan admits that he lacks experience with sling design. The fact that he has design "preferences" as a practicing doctor in itself does not render him an expert in product design. (Culligan Dep. [Docket 233-3 & 233-4], at 326:23). Therefore, I **FIND** that Dr. Culligan is not qualified to opine as to product design.

Id. at *67–68. Accordingly, I **ADOPT** my prior ruling, as stated in *Tyree*, and **FIND** that Dr. Culligan is not qualified to opine on the design of the Obtryx. These opinions are **EXCLUDED**. As a result, I need not address the reliability of Dr. Culligan's opinions related to product design.

3. Obtryx DFU

Next, the plaintiff argues that Dr. Culligan may not offer expert opinions on the Obtryx DFU. The plaintiff contends that Dr. Culligan lacks the necessary knowledge, skill, experience, training, or education to testify regarding the Obtryx DFU. In *Tyree*, I held as follows:

> As for qualifications, Dr. Culligan has "participated in the drafting of a DFU." (*Id.* at 260:4–5). However, he testified that he hired a regulatory consultant that wrote the first draft and that he "then . . . just worked on the specific wording for that document." (*Id.* at 260:13–16). Also, he admits that he is "not an expert in the drafting of DFUs." (*Id.* at 261:5–6). Dr. Culligan further testifies about his lack of expertise as to the inclusion of complication rates in DFUs:
>
> Q: In general, do directions for use include complications to your knowledge?
>
> A: I – I guess I can't really answer for all directions of use. I'm not an expert

> on what directions of use are supposed to include. I'm thinking about my knowledge of my own, you know, document and certainly include information about how to avoid or by the proper use implying how to avoid complications. I – you know, I'm not sure –
>
> Q: Okay. Fair enough.
>
> A: -- what you want.
>
> (*Id.* at 305:16–306:8) (objections omitted). Dr. Culligan does not have the "knowledge, skill, experience, training, or education" to opine as to the Obtryx DFU. Fed. R. Evid. 702; *see In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 607 (S.D. W. Va. 2013) (finding Dean Altenhofen, M.D., unqualified to opine as to adequacy of warnings). Therefore, I **FIND** that Dr. Culligan is unqualified to testify as to these opinions.

Id. at *68–69. Accordingly, I **ADOPT** my prior ruling, as stated in *Tyree*, and **FIND** that Dr. Culligan is not qualified to opine on the Obtryx DFU. These opinions are **EXCLUDED**. As a result, I need not address the reliability of Dr. Culligan's opinions related to the Obtryx DFU.[7]

4. Patient Brochures

Lastly, the plaintiff argues that Dr. Culligan may not offer expert opinions on the Obtryx patient brochure. The defendant concedes that Dr. Culligan will not opine on patient brochures because they are not relevant to this case. Accordingly, the plaintiff's motion with regard to patient brochures is **DENIED as moot**.

In sum, the plaintiff's motion with regard to Dr. Culligan is **GRANTED in part** and **DENIED as moot in part**.

B. Motion to Limit the Opinions and Testimony of Peter Finamore, M.D.

The plaintiff seeks to limit the expert opinions offered by Peter Finamore, M.D. Dr. Finamore is a practicing urogynecologist who opines that "Katherine Hall's complaints as

[7] I also note that the dismissal of the plaintiff's failure-to-warn claim renders Dr. Culligan's opinions related to the Obtryx DFU irrelevant and therefore inadmissible. *See Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.").

alleged in this lawsuits were not caused by the Obtryx sling." (Finamore Report [Docket 116-2], at 34). The plaintiff contends that the court should limit Dr. Finamore's opinions on the following subjects: (1) the Obtryx DFU; (2) the FDA 510(k) approval process; (3) the Obtryx patient brochure; (4) Ms. Hall's alleged failure to use estrogen cream; (5) Dr. Iakovlev's expert opinions; (6) social side effects; (7) Ms. Hall's history of smoking; (8) Ms. Hall's dependence on pain medication; and (9) unrelated comorbidities and family medical history.

1. Obtryx DFU

The plaintiff argues that Dr. Finamore's opinions on the Obtryx DFU and IFU should be excluded because he lacks the necessary knowledge, skill, experience, training, or education, and his opinions are not supported by a reliable foundation. I have previously reviewed a similar argument with regard to the adequacy of warnings. *See Tyree*, 2014 WL 5320566 at *70-71. In *Tyree*, I held as follows:

> Author and astronomer, Carl Sagan, popularized the aphorism, "Absence of evidence is not evidence of absence." Carl Sagan, *The Demon-Haunted World: Science as a Candle in the Dark* 213 (1996). Sagan's aphorism illustrates the logical fallacy that a premise is not necessarily true merely because it has yet to be proven false. Instead, there is often insufficient investigation and information to come to a conclusive determination. Sagan's musings are relevant here because for the first time during these MDLs, the plaintiffs have challenged the defendant's attempt to offer experts seeking to opine on the adequacy of product warnings. In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not

> qualified to opine that a product warning was adequate, merely because it included the risks he has observed in his own practice.

Id.

In his expert report, Dr. Finamore discusses the risks of pelvic surgery and states that "Boston Scientific adequately warned of these risks, as all such risks are identified in the Directions for Use (DFU) accompanying the Obtryx sling." (Finamore Report [Docket 116-2], at 11 (referring to the following potential complications: pain, inflammation, infection, failure of the procedure to cure the incontinence or prolapse, urinary difficulties, dyspareunia, abscess, and injury to vessels, nerves, muscles, bladder, and/or bowel)). Dr. Finamore fails to address the significance of any complications not listed in his report and not warned of in the DFU. In his deposition, Dr. Finamore admits that he has never drafted a DFU and that he only intends to opine on the Obtryx DFU "as it relates to [his] own clinical practice." (Finamore Dep. [Docket 116-3], at 132). Accordingly, I **FIND** that Dr. Finamore is not qualified to opine on the adequacy of product warnings, and therefore, his opinions related to the Obtryx DFU are **EXCLUDED**.[8]

2. FDA 510(k) Process

The plaintiff argues that Dr. Finamore's opinions on the FDA 510(k) approval process should be excluded because he lacks the necessary knowledge, skill, experience, training, or education to be qualified as an expert. BSC concedes that Dr. Finamore will not offer opinions on the FDA 510(k) approval process. Accordingly, the plaintiff's motion is **DENIED as moot**.

3. Obtryx Patient Brochure

The plaintiff argues that Dr. Finamore may not offer opinions on the Obtryx patient brochure or on patient labeling because no such opinions were disclosed in his Rule 26 Report.

[8] I also note that the dismissal of the plaintiff's failure-to-warn claim renders Dr. Finamore's opinions related to the Obtryx DFU irrelevant and therefore inadmissible. *See Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.").

BSC concedes that Dr. Finamore will not opine on patient brochures because they are not relevant to this case. Accordingly, the plaintiff's motion is **DENIED as moot**.

4. Estrogen Cream

The plaintiff argues that Dr. Finamore's opinions regarding Ms. Hall's alleged failure to use estrogen cream should be excluded because they are unreliable. In support of this argument, the plaintiff cites to Dr. Finamore's deposition testimony, where he admits that he is unsure of the exact dates when Ms. Hall began using the estrogen cream. (Finamore Dep. [Docket 116-3], at 361-63). However, in his expert report, Dr. Finamore explains that a lack of estrogen can cause atrophic vaginitis, which results in thin and dry vaginal tissue. (Finamore Report [Docket 116-2], at 28-29). Based on this knowledge, Dr. Finamore concludes "that decrease in estrogen and treatment non-compliance with local hormone replacement significantly contributed to Ms. Hall's mesh exposure." (*Id.* at 29). Ms. Hall's medical records clearly indicate that she did not use the vaginal estrogen. (*Id.* at 28). Whether Dr. Finamore is aware of the exact date when Ms. Hall began using the estrogen cream is not sufficient to render his opinions unreliable under *Daubert*. Accordingly, the plaintiff's motion with regard to estrogen cream is **DENIED**.

5. Dr. Iakovlev

The plaintiff argues that Dr. Finamore's opinions attacking Dr. Iakovlev should be excluded because Dr. Finamore is unqualified to opine on pathology. As discussed more fully *supra*, I have **EXCLUDED** Dr. Iakovlev's specific causation opinions. Accordingly, the plaintiff's motion with regard to Dr. Iakovlev is **GRANTED**, and these opinions are **EXCLUDED** as irrelevant.

6. Social Side Effects

The plaintiff argues that Dr. Finamore's opinions on the social side effects of urinary

incontinence should be excluded as irrelevant because Ms. Hall did not suffer from the described conditions. In response, BSC contends that Dr. Finamore's opinions are relevant to whether the Obtryx is "unreasonably dangerous" and to BSC's affirmative defenses. Regardless, Dr. Finamore's description of "social implications" associated with incontinence does not require the use of "scientific, technical, or other specialized knowledge." Fed. R. Evid. 701. Therefore, I will not address the admissibility of these opinions here and **RESERVE** this ruling for trial.

7. Smoking

The plaintiff argues that Dr. Finamore may not opine on Ms. Hall's history of smoking because no such opinions were disclosed in his expert report. Under Rule 26, expert reports must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Accordingly, the plaintiff's motion with regard to smoking is **GRANTED**, and these opinions are **EXCLUDED**.

8. Pain Medication

The plaintiff argues that Dr. Finamore is unqualified to opine that Ms. Hall is dependent on pain medication. However, Dr. Finamore does not appear to offer such an expert opinion. In his report, Dr. Finamore describes Ms. Hall's medical history, including her history of chronic pain and treatment. He notes that "other doctors" have questioned whether or not Ms. Hall is dependent on pain medication, but he does not form his own opinion on the subject. (*See* Finamore Report [Docket 116-2], at 36-37). Similarly, in his deposition, Dr. Finamore explicitly states that he does not know whether Ms. Hall was addicted to pain medication. (Finamore Dep. [Docket 116-3], at 419). Accordingly, the plaintiff's motion with regard to pain medication is **DENIED as moot**.

9. Comorbidities and Family Medical History

The plaintiff argues that Dr. Finamore's opinions on Ms. Hall's unrelated "comorbidities" and family medical history should be excluded as irrelevant and not helpful to the trier of fact. While I believe that evidence of Ms. Hall's prior medical conditions may be relevant to the elements of causation and damages, I agree with the plaintiff that Dr. Finamore does not reliably link certain conditions, like neck pain and fibromyalgia, to Ms. Hall's injuries in this case. (*See* Finamore Dep. [Docket 116-3], at 387 ("As I said before, I mean, I can rationalize in my head how back pain and – to a lesser extent neck pain can [a]ffect the pelvic floor muscles, but I think that it's less related to her current list of complaints as opposed to I think more related to sort of an overall statement of a woman who suffers from multi-systems that are chronically causing her pain."); *see also id.* at 390 ("And so I think – and I don't think there's any great amount of literature to support his, because a lot of people don't publish on pain, and pelvic pain, but I can certainly say anecdotally from my experience that pelvic – chronic pelvic muscle pain is seen fairly reasonably often with patients with fibromyalgia.")). Accordingly, the plaintiff's motion with regard to comorbidities is **GRANTED**, and these opinions are excluded.

With regard to Ms. Hall's family medical history, Dr. Finamore is merely reciting facts, which does not require the use of "scientific, technical, or other specialized knowledge." Fed. R. Evid. 701. Therefore, I will not address the admissibility of these opinions here and **RESERVE** this ruling for trial.

In sum, the plaintiff's motion with regard to Dr. Finamore is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

C. Motion to Exclude or Limit the Testimony of Defendant Boston Scientific Corporation's Expert Christine Brauer, Ph.D.

The plaintiff seeks to exclude or limit the expert opinions of Christine Brauer, Ph.D. Dr. Brauer is a former FDA employee and regulatory consultant who offers opinions regarding the FDA regulatory process and BSC's regulatory activities. I have previously reviewed the opinion testimony of Dr. Brauer under *Daubert*. *See Sanchez*, 2014 WL 4851989, at *36–37. While the parties in this case have not relied on precisely the same arguments, my reasoning and conclusions from *Sanchez* still govern. Furthermore, to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. In *Sanchez*, I ruled as follows:

> I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, at 753–56 (S.D. W. Va. 2014). Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court. *See, e.g., Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 U.S. Dist. LEXIS 102699, at *22 (S.D. W. Va. July 23, 2013) ("The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no operative interaction with state tort laws.") (internal reference omitted); Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. July 1, 2013), [Docket 309], at 3–4 ("Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective . . . . Because the FDA 510(k) process does not go to whether the [mesh] products are safe and effective and the 510(k) process does not impose any requirements on its own, the 510(k) process is inapplicable to this case. This evidence is excluded under Federal Rule of Evidence 402 as irrelevant, and under Rule 403 for the reasons previously stated, including the very substantial dangers of misleading the jury and confusing the issues."); Mem. Op. & Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. June 27, 2013) [Docket 302], at 3–4 (holding that evidence regarding the 510(k) process and enforcement should be excluded under Rule 403); Mem. Op. & Order, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201 (S.D. W. Va. May 12, 2014 [Docket 223], at 1 ("This is not the first time I am confronted with determining the admissibility of evidence relating to marketing clearance under the FDA's 510(k) process . . . In all previous cases, I excluded all evidence relating to the 510(k) process because it does not go to the safety and efficacy of medical devices and because of the potential to mislead and confuse the jury."). Accordingly, I **FIND** that Dr. Brauer's opinions should be excluded in their entirety.

Id. at *36–37. Therefore, I **ADOPT** my prior ruling on Dr. Brauer, as stated in *Sanchez*, and **EXCLUDE** her opinions in their entirety. BSC's Motion to Exclude or Limit the Testimony of Dr. Brauer [Docket 118] is **GRANTED**.

D. Motion to Clarify

The plaintiff has also moved for the court to clarify its ruling set forth in *Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014). Specifically, the plaintiff asks the court to clarify its order with respect to Dr. Michael Thomas Margolis and Dr. Thomas Barker. I have previously addressed the concerns raised by the plaintiff regarding these rulings. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 5320599 (S.D. W. Va. Oct. 17, 2014). I direct the plaintiff to this order, which speaks to the clarifications sought by the plaintiff, and I **DENY** the Motion to Clarify [Docket 155].

V. Conclusion

To reiterate: BSC's Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [Docket 55]; Motion to Exclude the Opinions and Testimony of Richard W. Trepeta, M.D. [Docket 84]; Motion to Exclude the Opinions and Testimony of Donald R. Ostergard, M.D. [Docket 89]; Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. and Samuel P. Gido, Ph.D. [Docket 99]; and Motion to Exclude the Testimony of Peggy Pence [Docket 130] are **GRANTED in part** and **DENIED in part**. BSC's Motion to Exclude the Opinions and Testimony of Alison Vredenburgh, Ph.D., CPE [Docket 57]; Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 69]; Motion to Exclude the Opinions and testimony of Thomas H. Barker [Docket 72]; and Motion to Exclude the Testimony of Mark Slack [Docket 120] are **GRANTED**. And BSC's Motion to Exclude the

Plaintiffs' Experts' Opinions that Polypropylene Mid-Urethral Slings Are Defective [Docket 93] is **DENIED**.

The plaintiff's Motion to Limit the Opinions and Testimony of Patrick Culligan, M.D. [Docket 91] is **GRANTED in part** and **DENIED as moot in part**. The plaintiff's Motion to Limit the Opinions and Testimony of Peter Finamore, M.D. [Docket 116] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**. The plaintiff's Motion to Exclude or Limit the Testimony of Defendant Boston Scientific Corporation's Expert Christine Brauer [Docket 118] is **GRANTED**. The plaintiff's Motion to Clarify [Docket 155] is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 27, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE